English Translation of the Second Office Action

Application No.: 200480035389.8

The applicant submitted the response and the amended application documents on October 6, 2008 for responding to the first Office Action. The examiner further made the following comments after examination.

1. The applicant amended claim 1 into "*a drug mixing system comprising at least two of the following three components*". Thus, the new claim 1 contains such a technical solution that "the drug mixing system comprises at least one receptacle port adaptor and at least one syringe adaptor, no vial adaptor". However, this technical solution is not explicitly mentioned in the initial description and claims, and can not be directly and unambiguously derived by virtue of the contents described in the initial description and claims. Therefore, the amendments to claim 1 go beyond the scope of the disclosure described in the initial application, which does not meet the requirement of Article 33 of the Chinese Patent Law.

To economize on procedure, the following comments are made based on the technical solutions of claim 1 that do not go beyond the scope of the initial disclosure.

Claim 1 lacks inventiveness under Article 22(3) of the Chinese Patent Law.

Reference D1 (WO0035517A) discloses a drug mixing system, comprising: at least one receptacle port adaptor (14a) adapted to be inserted into a port of a fluid receptacle (3a); at least one vial adaptor (4c) adapted for connection to a vial (5c) containing a drug; and at least one syringe adaptor (2a) adapted to be attached to a syringe (1a) and to at least one of said at least one receptacle port adaptor and said at least one vial adaptor (see line 15 on page 7 to line 2 on page 10 of the description, and Figs. 1-2 of D1).

Thus, claim 1 differs from D1 in that: at least one of said components is vented to the atmosphere through a filter system preventing release to the atmosphere of possibly harmful contents of said vial in a liquid, solid or gaseous form. However, this distinguishing technical feature has been disclosed by Reference D2 (CN1237892A, WO98/13006) (see line 11 on page 3 to line 20 on page 5 of the description, and Figs. 1 to 4, particularly referring to the connecting device 1 and the filter 8). Moreover, this feature performs the same function in D2 as in the present invention, and D2 and the present invention fall into the same technical field. That is to say, there exists a technical teaching in D2 as to apply this feature to D1 in solving its technical problem or achieving the same technical effect. Then a person skilled in the art has a motivation to combine D2 with D1 to reach the technical solution defined in claim 1. For the skilled person, it is obvious that the technical solution defined in claim 1 can be reached on the basis of D1 and in combination with D2. Accordingly, as compared with D1 and D2 combination, claim 1 fails to have prominent substantive features and represent a notable progress, and thereby does not involve an inventive step under

Article 22(3) of the Chinese Patent Law.

2. Claim 2 lacks inventiveness under Article 22(3) of the Chinese Patent Law.

Claim 2 refers to claim 1. The additional technical feature of claim 2 has been correspondingly disclosed by Reference D3 (US4759756A) (see line 51 of column 5 to line 26 of column 11 of the description, and Figs. 1-6). Moreover, this feature performs the same function in D3 as in the present invention, i.e., connecting the vial to the receptacle. Thus, the technical solution defined in claim 2 is obvious to the skilled person. Therefore, when claim 1 lacks inventiveness, the dependent claim 2 also does not involve an inventive step under Article 22(3) of the Chinese Patent Law.

3. Claim 3 lacks inventiveness under Article 22(3) of the Chinese Patent Law.

Claim 3 refers to claim 1. The additional technical feature of claim 3 has been correspondingly disclosed by D2 (see line 11 on page 3 to line 20 on page 5 of the description, and Figs. 1-4), which feature performs the same function in D2 as in the present invention. Therefore, when claim 1 lacks inventiveness, the dependent claim 3 also does not involve an inventive step under Article 22(3) of the Chinese Patent Law.

4. Claim 4 lacks inventiveness under Article 22(3) of the Chinese Patent Law.

Claim 4 refers to claim 1. The additional technical feature of claim 4 has been correspondingly disclosed by D1 (see Fig. 2 of D1), which feature performs the same function in D1 as in the present invention. Therefore, when claim 1 lacks inventiveness, the dependent claim 4 also does not involve an inventive step under Article 22(3) of the Chinese Patent Law.

5. Claim 5 lacks inventiveness under Article 22(3) of the Chinese Patent Law.

Claim 5 refers to claim 1. The additional technical feature of claim 5 is that "*said at least one vial adaptor includes a venting and sealing element, operative to allow air into said drug mixing system and adapted to prevent air from escaping from said drug mixing system*". However, in order to prevent release to the atmosphere of possibly harmful contents of the vial, the skilled person can readily envisage using a venting and sealing element operative to allow air into the drug mixing system and adapted to prevent air from escaping from the drug mixing system. Thus, the technical solution defined in claim 5 is obvious to the skilled person. Therefore, when claim 1 lacks inventiveness, the dependent claim 5 also does not involve an inventive step under Article 22(3) of the Chinese Patent Law.

6. Claim 6 lacks inventiveness under Article 22(3) of the Chinese Patent Law.

Claim 6 refers to claim 1. The additional technical feature of claim 6 has been disclosed by D2 correspondingly (see line 11 on page 3 to line 20 on page 5 of the

description, and Figs. 1-4), which feature performs the same function in D2 as in the present invention. Therefore, when claim 1 lacks inventiveness, the dependent claim 6 also does not involve an inventive step under Article 22(3) of the Chinese Patent Law.

7. Claims 7-9 lacks inventiveness under Article 22(3) of the Chinese Patent Law.

The additional technical features of claims 7 to 9 are the routine technical means in the art, and use of these routine technical means is obvious to the skilled person. Therefore, when the claim referred to lacks inventiveness, the dependent claims 7 to 9 also do not involve an inventive step under Article 22(3) of the Chinese Patent Law.

8. Claims 12 and 13 lacks inventiveness under Article 22(3) of the Chinese Patent Law.

In claims 12 and 13, the technical feature, "*the receptacle port adaptor includes a needle*", has been disclosed in D3 correspondingly (see Fig. 2 of D3), which feature performs the same function in D3 as in the present invention. Moreover, it the common technical means to cover the needle with an elastomer and to integrally form these adaptors. This is the common knowledge in the art. Therefore, when claim 1 lacks inventiveness, the dependent claims 12 and 13 also do not involve an inventive step under Article 22(3) of the Chinese Patent Law.

9. Claim 14 lacks inventiveness under Article 22(3) of the Chinese Patent Law.

Claim 14 refers to claim 1. The additional technical feature of claim 14 is the routine technical means in the art, and use of this routine technical means is obvious to the skilled person. Therefore, when claim 1 lacks inventiveness, the dependent claim 14 also does not involve an inventive step under Article 22(3) of the Chinese Patent Law.

10. Claim 15 lacks inventiveness under Article 22(3) of the Chinese Patent Law.

Claim 15 refers to claim 1. The additional technical feature of claim 15 has been correspondingly disclosed by D1 (see Fig. 2 of D1), which feature performs the same function in D1 as in the present invention. Therefore, when claim 1 lacks inventiveness, the dependent claim 15 also does not involve an inventive step under Article 22(3) of the Chinese Patent Law.

11. Claims 16 and 17 lack inventiveness under Article 22(3) of the Chinese Patent Law.

The additional technical features of claims 16 and 17 have been correspondingly disclosed by D3 (see line 51 of column 5 to line 26 of column 11 of the description, and Figs. 1-6). Moreover, these features perform the same function in D3 as in the present invention. Therefore, when the claim referred to lacks inventiveness, the dependent claims 16 and 17 also do not involve an inventive step under Article 22(3) of the

Chinese Patent Law.

12. Claim 18 lacks inventiveness under Article 22(3) of the Chinese Patent Law.

Claim 18 refers to claim 16. The additional technical feature of claim 18, "*the needle port adaptor includes a needle*", has been disclosed by D3 (see Fig. 2 of D3). This feature performs the same function in D3 as in the present invention. Moreover, it is the routine technical means to protect the needle by a needle protector. Therefore, when claim 16 lacks inventiveness, the dependent claim 18 also does not involve an inventive step under Article 22(3) of the Chinese Patent Law.

13. Claim 19 lacks inventiveness under Article 22(3) of the Chinese Patent Law.

Claim 19 refers to claim 18. The additional technical feature of claim 19 has been disclosed by D3 correspondingly (see line 51 of column 5 to line 26 of column 11 of the description, and Figs. 1-6), which feature performs the same function in D3 as in the present invention. Therefore, when claim 18 lacks inventiveness, the dependent claim 19 also does not involve an inventive step under Article 22(3) of the Chinese Patent Law.

14. Claim 20 lacks inventiveness under Article 22(3) of the Chinese Patent Law.

Claim 20 refers to claim 18. The additional technical feature of claim 20 is the common technical means in the art, and use of this routine technical means is obvious to the skilled person. Therefore, when claim 18 lacks inventiveness, the dependent claim 20 also does not involve an inventive step under Article 22(3) of the Chinese Patent Law.

15. Claim 23 lacks inventiveness under Article 22(3) of the Chinese Patent Law.

Claim 23 refers to claim 1. The additional technical feature of claim 23 has been correspondingly disclosed by Reference D4 (CN2126081U) (see page 3 of the description, and Fig. 1), which feature performs the same function in D4 as in the present invention. Therefore, when claim 1 lacks inventiveness, the dependent claim 23 also does not involve an inventive step under Article 22(3) of the Chinese Patent Law.

16. Claim 24 lacks inventiveness under Article 22(3) of the Chinese Patent Law.

Claim 24 refers to claim 1. The additional technical feature of claim 24 has been correspondingly disclosed by Reference D5 (CN2452515Y) (see page 3 of the description, and Fig. 1), which feature performs the same function in D5 as in the present invention. Therefore, when claim 1 lacks inventiveness, the dependent claim 24 also does not involve an inventive step under Article 22(3) of the Chinese Patent Law.

17. Claim 25 lacks inventiveness under Article 22(3) of the Chinese Patent Law.

Claim 25 refers to claim 1. The additional technical feature of claim 25 has been disclosed by D2 correspondingly (see line 11 on page 3 to line 20 on page 5 of the description, and Figs. 1-4), which feature performs the same function in D2 as in the present invention. Therefore, when claim 1 lacks inventiveness, the dependent claim 25 also does not involve an inventive step under Article 22(3) of the Chinese Patent Law.

18. Claim 26 lacks inventiveness under Article 22(3) of the Chinese Patent Law.

Claim 26 refers to claim 1. The additional technical feature of claim 26 has been disclosed by D1 correspondingly (see line 13 on page 8 to line 10 on page 9 of the description, and Fig. 2), which feature performs the same function in D1 as in the present invention. Therefore, when claim 1 lacks inventiveness, the dependent claim 26 also does not involve an inventive step under Article 22(3) of the Chinese Patent Law.

19. Claims 27 and 28 lack inventiveness under Article 22(3) of the Chinese Patent Law.

The additional technical features of claims 27 and 28 have been correspondingly disclosed by D3 (see Figs. 2, 5, 6). Moreover, these features perform the same function in D3 as in the present invention. Therefore, when the claim referred to lacks inventiveness, the dependent claims 27 and 28 also do not involve an inventive step under Article 22(3) of the Chinese Patent Law.

20. Claim 29 lacks inventiveness under Article 22(3) of the Chinese Patent Law.

Claim 29 refers to claim 1. The additional technical features of claim 29 have been disclosed by Reference D6 (US2003/181863A) correspondingly (see paragraphs [0020]-[0021] of the description, and Figs. 1-3 of D6). Moreover, these features perform the same function in D6 as in the present invention. Therefore, when claim 1 lacks inventiveness, the dependent claim 29 also does not involve an inventive step under Article 22(3) of the Chinese Patent Law.

21. Claim 6 recites that the drug mixing system also comprises a membrane vent. However, it is mentioned in claim 1, to which claim 6 refers, that the drug mixing system has a filter system. The filter system itself is a specific form of the membrane vent (see paragraph 4 of page 2 of the description). Therefore, claim 6 is not clear, which does not meet the requirement of Rule 20(1) of the Implementing Regulations of the Chinese Patent Law. When amending claim 6, the applicant shall make an adaptive amendment to claims 7 to 9.

The applicant shall make a response within the specified time limit and amend the application documents, especially the independent and dependent claims according to the cited reference documents. Also, the applicant shall state the reasons why the amended claims possess novelty and inventiveness as compared with the reference documents and the prior art. When amending the claims, the applicant shall make an adaptive amendment to the description. Please note the amendments to the application should be in conformity with the provisions of Article 33 of the Patent Law, and should not go beyond the scope of the disclosure contained in the initial description and claims.

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13.02.09

Reference	Application No./Patent No.
15525MNMms	04791853.7 - 1257 / 1687203 PCT/IL2004000993

Applicant/Proprietor
Teva Medical Ltd.

Proceeding further with the European patent application pursuant to Rule 70(2) EPC

A supplementary European search report has been drawn up concerning the above European patent application (publication number 1687203).

Since a request for examination has been filed (R. 70(1) EPC) and the examination fee has been paid (Art. 94(1) EPC) prior to the transmission of the supplementary European search report, you are hereby invited to indicate within

two months

of notification of this invitation whether you desire to proceed further with the European patent application.

If you do not indicate in due time that you desire to proceed further with the European patent application, it will be deemed to be withdrawn (R. 70(3) EPC).

If you wish you may comment on the supplementary European search report and amend, where appropriate, the description, claims and drawings (R. 70(2) EPC).

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Reference	Application No./Patent No.
15525MNMms	04791853.7 - 1257 / 1687203 PCT/IL2004000998
Applicant/Proprietor	
Teva Medical Ltd.	

Communication

The European Patent Office herewith transmits as an enclosure the supplementary European search report under Article 153(7) EPC for the above-mentioned European patent application.

If applicable, copies of the documents cited in the European search report are attached.

☑ 0 additional set(s) of copies of the documents cited in the European search report is (are) enclosed as well.

Refund of the search fee

If applicable under Article 9 Rules relating to fees, a separate communication from the Receiving Section on the refund of the search fee will be sent later.

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SUPPLEMENTARY EUROPEAN SEARCH REPORT

Application Number
EP 04 79 1853

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (IPC)
X	EP 1 145 702 A (NIPRO CORP [JP]) 17 October 2001 (2001-10-17) * paragraphs [0018], [0012], [0014]; figure 6 *	1,2, 5-14, 16-18, 22,24,25	INV. B65B1/04
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A	US 2002/087118 A1 (REYNOLDS DAVID L [CA] ET AL) 4 July 2002 (2002-07-04) * the whole document *	1-18, 22-31	TECHNICAL FIELDS SEARCHED (IPC) A61J

The supplementary search report has been based on the last set of claims valid and available at the start of the search.

Place of search	Date of completion of the search	Examiner
The Hague	20 January 2009	Bielsa, David

CATEGORY OF CITED DOCUMENTS

X: particularly relevant if taken alone
Y: particularly relevant if combined with another document of the same category
A: technological background
O: non-written disclosure
P: intermediate document

T: theory or principle underlying the invention
E: earlier patent document, but published on, or after the filing date
D: document cited in the application
L: document cited for other reasons

&: member of the same patent family, corresponding document

EPO FORM 1503 03.82 (P04C04)

CLAIMS INCURRING FEES

The present European patent application comprised at the time of filing claims for which payment was due.

☐ Only part of the claims have been paid within the prescribed time limit. The present European search report has been drawn up for those claims for which no payment was due and for those claims for which claims fees have been paid, namely claim(s):

☐ No claims fees have been paid within the prescribed time limit. The present European search report has been drawn up for those claims for which no payment was due.

LACK OF UNITY OF INVENTION

The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

see sheet B

☐ All further search fees have been paid within the fixed time limit. The present European search report has been drawn up for all claims.

☐ As all searchable claims could be searched without effort justifying an additional fee, the Search Division did not invite payment of any additional fee.

☐ Only part of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the inventions in respect of which search fees have been paid, namely claims:

☐ None of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the invention first mentioned in the claims, namely claims:

☒ The present supplementary European search report has been drawn up for those parts of the European patent application which relate to the invention first mentioned in the claims (Rule 164 (1) EPC).

The Search Division considers that the present European patentapplication does not comply with the requirements of unity of invention and relates to severalinventions or groups of inventions, namely:

1. claims: 1-18,22-31

A drug handling system comprising en element including atmospheric venting functionality that prevents release of the atmosphere of potentially harmful drug material.

---

2. claims: 19-21

A syringe adaptor comprising a septa housing wherein at least one septum is enclosed, and,a needle including a tip in said septa housing when said syringe adaptor is not connected to other element.

Document US-A-2002/0087118 discloses an reconstituting delivery system with a syringe adaptor comprising a needle and a vial adaptor (see description 11, 12 and figure 2)

The special technical features, as defined in Rule 44 EPC, of the first group of claims, which are intended to be a contribution over this prior art, i.e. the atmospheric venting functionality, apparently solve the problem of the overpressure in the vial when fluid is entered therein.

The special technical features, as defined in Rule 44 EPC, of the second group of claims, which are intended to be a contribution over said prior art, i.e. the tip of the needle being located in the septa housing, apparently solve the problem of the possible contamination of the tip of the needle due to its exposure.

No same or similar special technical features can be determined and different underlying problems are solved. Moreover, it is clear that the 2 claimed inventions can be applied independently of each other, i.e they are not necessarily inter-related.

It appears therefore that no technical relationship between the various claimed inventions exists involving one or more of the same or corresponding special technical features. The 2 groups of claims are thus not so linked as to form a single general inventive concept.

ANNEX TO THE EUROPEAN SEARCH REPORT ON EUROPEAN PATENT APPLICATION NO. EP 04 79 1853

This annex lists the patent family membersrelating to the patent documents cited in the above-mentioned European search report. The members are as contained in the European Patent Office EDP file on
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20-01-2009

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EPO FORM P0459

US 20030181863A1

D6

(19) United States
(12) Patent Application Publication (10) Pub. No.: US 2003/0181863 A1
Ackley et al. (43) Pub. Date: Sep. 25, 2003

(54) MICRONEEDLE ADAPTER

(76) Inventors: Donald E. Ackley, Cardiff, CA (US); Shawn Davis, Smyrna, GA (US); Thomas Jackson, La Jolla, CA (US)

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(21) Appl. No.: 10/412,384

(22) Filed: Apr. 11, 2003

Related U.S. Application Data

(63) Continuation-in-part of application No. PCT/US01/46845, filed on Nov. 8, 2001.

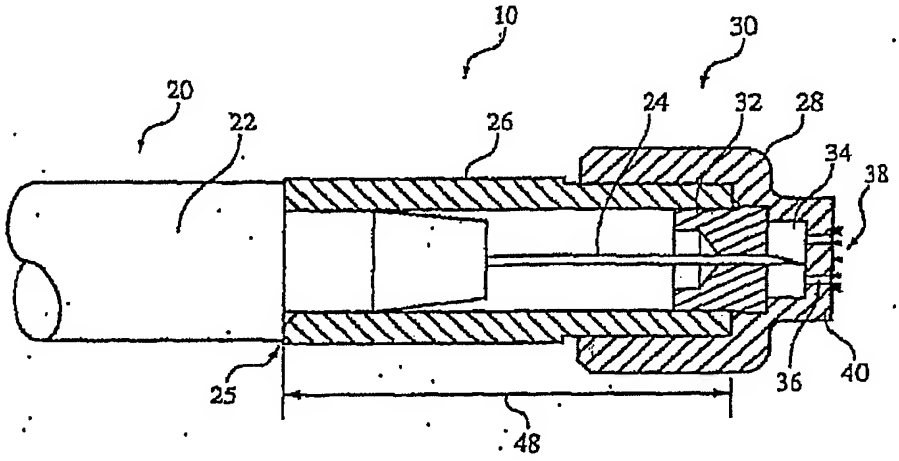
(60) Provisional application No. 60/247,571, filed on Nov. 9, 2000.

Publication Classification

(51) Int. Cl.[7] A61M 5/24
(52) U.S. Cl. 604/201; 604/205

(57) ABSTRACT

The present invention relates to an adapter for the transport of fluids with a microneedle device. The adapter can receive a syringe, for example, that is used to transport a fluid through the adapter for injection into a patient using the microneedle device. The adapter can include a seal through which a syringe needle is inserted to deliver fluid from the syringe into a fluid cavity in the adapter.



D3

United States Patent [19]

Forman et al.

[11] Patent Number: 4,759,756

[45] Date of Patent: Jul. 26, 1988

[54] RECONSTITUTION DEVICE

[75] Inventors: Hugh M. Forman, Waukesha, Wis.; Donald B. Williams, Chicago, Ill.

[73] Assignee: Baxter Travenol Laboratories, Inc., Deerfield, Ill.

[21] Appl. No.: 650,481

[22] Filed: Sep. 14, 1984

[51] Int. Cl.[4] A61J 1/00; A61J 5/00; A61M 5/32

[52] U.S. Cl. 604/413; 604/88

[58] Field of Search 604/56, 411, 412, 413, 604/414, 415, 416, 88

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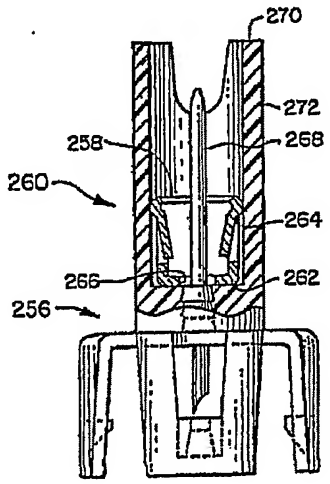
Primary Examiner—John F. Niebling
Assistant Examiner—Ben C. Hsing
Attorney, Agent, or Firm—Paul C. Flattery; Bradford R. L. Price

[57] ABSTRACT

Various embodiments of an improved reconstitution device 30, 168, 170, 186, 242, 256, 274 are disclosed, directed to the proper mixing of two substances, and are particularly directed to the medical field for the reconstitution of a drug 36 which may be stored in a drug vial 32 with a diluent 60 stored in a flexible medical solution container 34 and used for the intravenous delivery of a medicament. In one embodiment the reconstitution device 30 includes an improved vial adapter 76 and bag adapter 78 which permit the permanent coupling of the vial 32 and liquid container 34. The bag adapter 78 may be rotatable relative to the vial adapter 76 to operate a valve including a stem channel 108 and a base post 148 on the vial adapter 76, a base segment channel 136 and a cut out portion 146 of a rim 140 on the bag adapter 78, and a sealing segment 80 disposed between the vial and bag adapter 76, 78. The reconstitution device 30 reduces drug waste in hospitals, eliminates the need to relabel parenteral solution containers after a drug has been added, and prevents repeated exposure of hospital personnel to various drugs.

2 Claims, 8 Drawing Sheets



Dec. 26, 1967 G. K. BURKE 3,359,977

AIR FILTER MEANS

Filed March 19, 1965

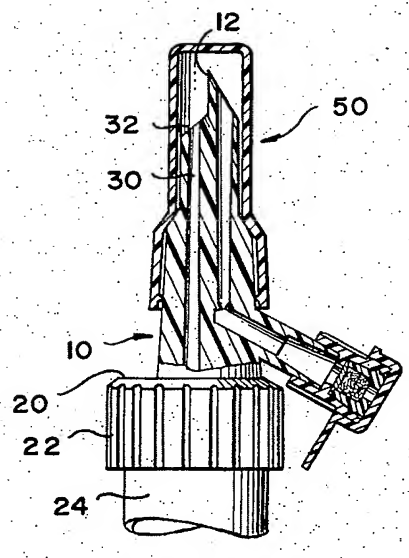


FIG. 1

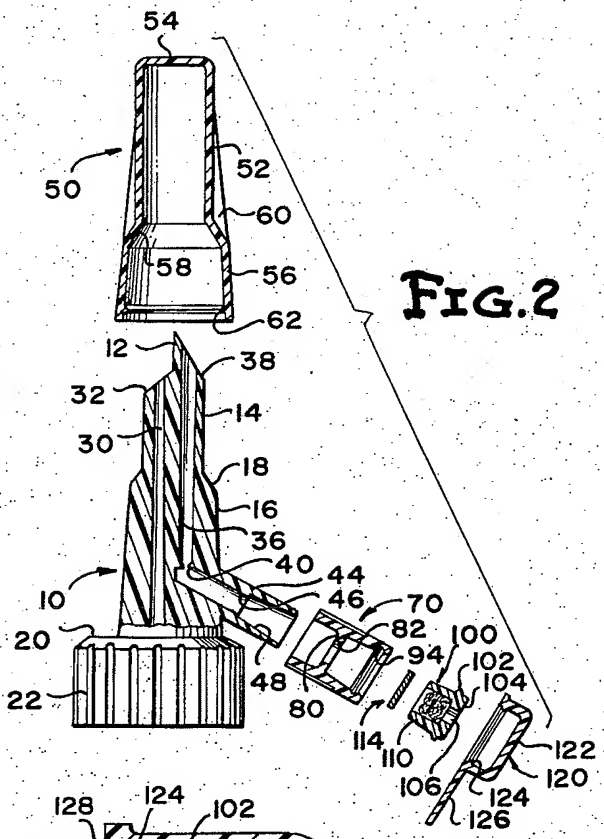


FIG. 2

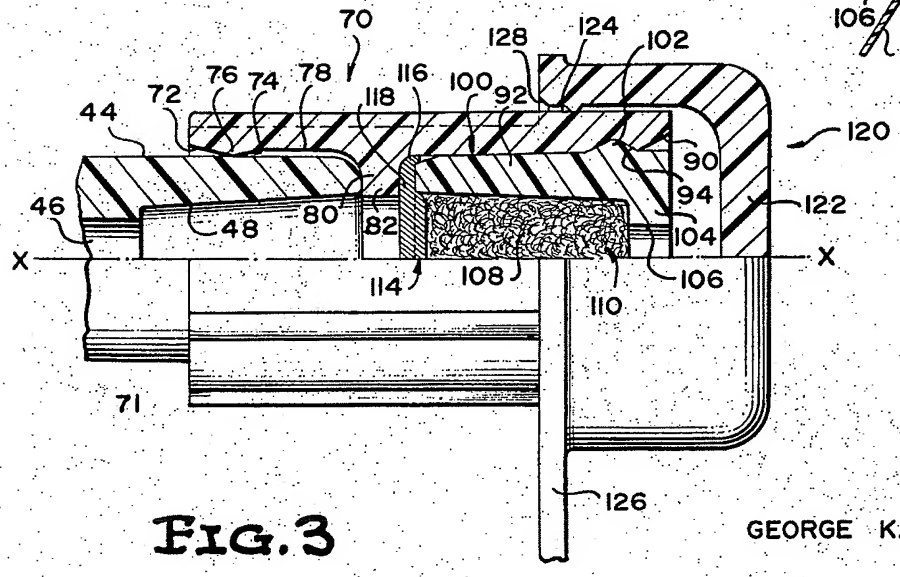


FIG. 3

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(54) **PHARMACEUTICAL DELIVERY SYSTEM**

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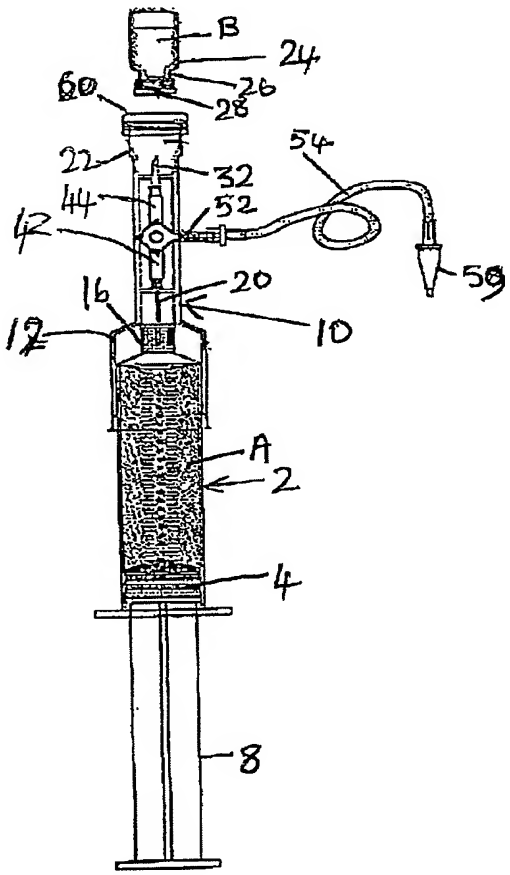
(57) **ABSTRACT**

A pharmaceutical delivery system for reconstituting and delivering a two-part pharmaceutical composition through a catheter, consisting of a first container, typically a syringe, for containing a first component of a pharmaceutical, with a first broachable closure closing the container, and a fluid displacement apparatus configured to move fluid into and out of the container through the broachable closure; a second container containing a second component of the pharmaceutical, with a second broachable closure closing the container; a body comprising first, second and third open-ended vessels extending from the diverter valve operative to alternatively connect the first and second vessels or the first and third vessels; the first vessel communicating with a socket for receiving at least a part of the first container, including the broachable closure of the first container, the socket containing a first closure broaching member such as a cannula; the second vessel communicating with a socket for receiving at least a part of the second container, including the broachable closure of the second container; the socket containing a second closure broaching member such as a cannula. The third vessel is connected to a tubulation for delivery of the reconstituted pharmaceutical, which tubulation may, in one embodiment, also be used for filling the first container.



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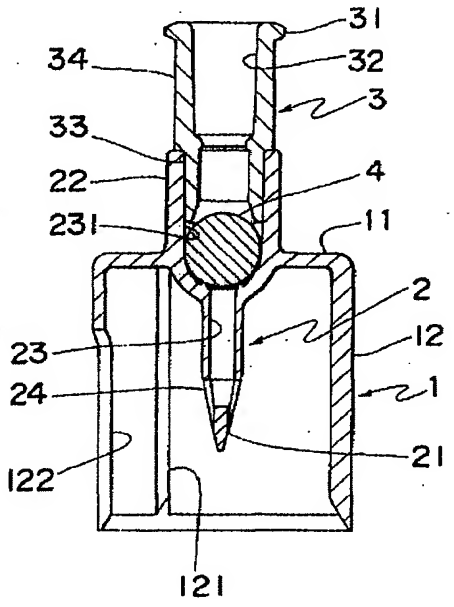
(54) Adapter for mixing and injection of preparations

(57) An adapter for mixing and injection of preparations comprises a cylindrical vial-fitting portion (1), a puncture needle (2) and a tubular tip-fitting portion (3). The vial-fitting portion (l) includes a top wall (11) and a skirt (12). The puncture needle (2) is passed through the top wall (11) and is integrated therewith. The tip-fitting portion (3) is arranged coaxially to the puncture needle (2) on the opposite side thereof to the top wall (11). The puncture needle (2) has a cutting edge (21) on the side of the skirt (12) and is provided at a proximal end thereof with a connecting portion (22) for engagement with the tip-fitting portion (3). The puncture needle (2) has a fluid passage (23), which communicates with a lumen (32) of the tip-fitting portion (3) and is open to the cutting edge (21). A filter (4) is arranged in the liquid passage (231) of the connecting portion (22).

Fig. 3



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Description

[0001] The present invention relates to an adapter for mixing and injection of preparations. More particularly, the present invention relates to an adapter for transferring a drug solution or solvent from a syringe to a vial including a dried medicine such as a powdered preparation or a solid preparation charged therein to mix them to prepare a dose of a mixed medical solution and for transferring the resultant medical solution in the vial to the syringe.

[0002] Freeze-dried medicines such as powdered preparations or solid preparations are generally stored in vials. In the prior art, such preparations are mixed with a solvent or drug solution, for example, by connecting a vial to a solvent vessel with a double-ended needle to form liquid communication between them, transferring the solvent from the solvent vessel to the vial to dissolve the dried medicine in the solvent, and collecting a certain amount of the resultant drug solution by a syringe through a needle attached thereto.

[0003] However, the above method takes a long time to fill the syringe with the resultant drug solution by suction because of a minor diameter of the needle to be used. Further, in order to avoid risk of an accident due to use of an edged metal needle, it is difficult to operate.

[0004] In order to solve such disadvantages, it has been proposed in Japanese patent unexamined publication JP-A 7-213585 to use an adapter for liquid transfer and injection, which is connectable to both a vial and a syringe and makes it possible to transfer the liquid without use of any syringe needle. This adapter comprises a cylindrical hub coaxially provided at one end thereof with a hollow puncture needle and at the opposite end with a tubular tip-fitting portion. At the peripheral part of the hub, there are provided a vial-fitting portion and a syringe-connecting portion, which are respectively coaxial to the puncture needle and the tip-fitting portion. The puncture needle is provided with a medicine channel communicated with the tip-fitting portion, and a gas channel being open to a vent hole with a filter for separation of microorganisms provided in the vial-fitting portion.

[0005] However, the above adapter for liquid transfer and injection has a danger of contamination in the medical solution with foreign substances due to coring which may occur by puncture of a rubber stopper with the puncture needle.

[0006] In view of the above circumstances, the present invention has been made to provide an adapter for mixing and injection of preparations, which makes it possible to remove foreign substances get into a medical solution in case of operation to dissolve a dose of a solid preparation in a solvent by use of the adapter.

[0007] According to the present invention, the above object is achieved by providing an adapter with a filter, in particular, by providing a connecting portion for attachment to the tip-fitting portion at a proximal end of a puncture needle and arranging a filter in the connecting portion. This makes it possible to provide a filter in the adapter with ease and certainty.

[0008] In other words, the present invention provides an adapter for mixing and injection of preparations comprising:

a vial-fitting portion having a top wall and a skirt portion;

a puncture needle passed through the top wall 11 of the vial-fitting portion 1 and integrated therewith, said puncture needle having a cutting edge on the side of said skirt; and

a tubular tip-fitting portion located coaxially to the puncture needle on the opposite side thereof to the top wall,

wherein said puncture needle has at a proximal end thereof a connecting portion for connection with the tip-fitting portion and a liquid passage which communicates with a lumen of the tip-fitting portion and is open to the cutting edge of the puncture needle, said connecting portion being provided at a liquid passage thereof with a filter.

[0009] In order to facilitate the transfer of liquid from a syringe to a vial or vice verse, the puncture needle may be provided with a gas passage running through the puncture needle and being open to the cutting edge while the connecting portion of the puncture needle may be provided with a vent hole having a filter for separation of microorganisms and being communicated with the gas passage. In this case, it is preferred to provide a check valve, which allows the gas to flow only in the direction of the gas passage, adjacent to the filter in the vent hole on the inside of the filter, so as to prevent the medical solution from flowing into the vent hole through the gas passage when the vial is reversed.

[0010] Further, in order to facilitate the attachment of the vial to the adapter, the vial-fitting portion may be provided in its skirt with one or more vertical slit.

[0011] The invention will be understood by reference to the following description, taken in conjunction with the accompanying drawings, which show, by way of example only, preferred embodiments of the present invention.

Fig. 1 is a plane view of an adapter for mixing and injection of preparations illustrating one embodiment of the present invention;

Fig. 2 is a bottom view of the adapter shown in Fig. 1;

Fig. 3 is a section view of the adapter taken along a line X-X in Fig. 2;

Fig. 4 is a plane view illustrating another embodiment of the adapter according to the present invention;

Fig. 5 is a bottom view of the adapter shown in Fig. 4;

Fig. 6 is a section view of the adapter taken along a line Y-Y in Fig. 5; and

Fig. 7 is a side view illustrating how to use the adapter of Fig. 1.

[0012] Referring now to Figs. 1 to 3, there is illustrated one embodiment of an adapter for mixing and injection of preparations according to the present invention, which comprises a cylindrical vial-fitting portion 1, a puncture needle 2, and a tubular tip-fitting portion 3. The vial-fitting portion 1 includes a top wall 11 and a skirt 12. The puncture needle 2 is passed through the top wall 11 and is integrated therewith. On the other hand, the tip-fitting portion 3 is arranged coaxially to the puncture needle 2 on the opposite side thereof to the top wall 11 and connected to the proximal end of the puncture needle 2.

[0013] The puncture needle 2 has a cutting edge 21 on the side of the skirt 12 and is provided at a proximal end thereof with a connecting portion 22 for engagement with the tip-fitting portion 3. The puncture needle 2 has a fluid passage 23, which communicates with a lumen 32 of the tip-fitting portion 3 and is open to the cutting edge 21. A filter 4 is arranged in the liquid passage 231 of the connecting portion 22.

[0014] The vial-fitting portion 1 is a cylindrical member made of a flexible material such as polypropylene, polyethylene, ABS resin, polycarbonate resin, polystyrene resin or the like and having the top wall 11 and skirt 12. The skirt 12 is provided on an inner wall thereof with three or five longitudinal ribs 121 to enhance the engagement force with the vial (not illustrated in the drawings). Further, the skirt 12 may be provided with one or more longitudinal slit 122 to facilitate insertion of the vial.

[0015] The puncture needle 2 is passed through the top wall 11 of the vial-fitting portion 1 and integrated therewith. The puncture needle 2 has a cutting edge 21 on the side of the skirt 12 of the vial-fitting portion 1 and has a connecting portion 22 for attachment of the tip-fitting portion 3 at the proximal end thereof. The needle has a liquid passage 23, which communicates with a lumen 32 of the tip-fitting portion 3 and is open to the cutting edge 21 through side holes 24. The liquid passage 23 is increased in diameter at the connecting portion 22 to form a large-sized liquid passage 231. Arranged in the large-sized liquid passage 231 is a filter 4 for removal of foreign substances due to coring, which may occur by puncture of a rubber stopper in a mouth of the vial with the puncture needle 2.

[0016] The filter 4 may take any shape and may be made of any material, provided that it can remove the foreign substances. It is preferred to use a layered material of wire netting, fibers or sintered compact of resin. The filter 4 may be formed into a spherical body as illustrated in Fig. 3. In this case, since the filter 4 has no orientation, it is easy to arrange the filter 4 in the connecting portion 22. Further, when fitting the separate tip-fitting portion 3 in the connecting portion 22, it is possible to fix the filter 4 in position by forcing the filter 4 toward a seating portion therewith.

[0017] The tip-fitting portion 3 may be formed as an integral part of the vial-fitting portion 1 and the puncture needle 2. Preferably, the tip-fitting portion 3 may be formed as a discrete member separated from the vial-fitting portion 1 and the puncture needle 2 as illustrated in Fig. 3. In this case, tip-fitting portion 3 is composed of a distal portion 33 to be fitted in the connecting portion 22 of the puncture needle 2, and a proximal portion 34 to be connected to a tip C of a syringe S illustrated in Fig. 7. The proximal portion 34 may be provided at a proximal end thereof with a double-start thread 31 as an engaging means, if necessary. In this case, it is possible to fix a syringe with a female engaging means (not illustrated in the drawings) on the tip C.

[0018] As illustrated in Figs. 4 to 6, the puncture needle 2 may be provided with a gas passage 25 being open to the cutting edge 25 and a vent hole 26 having a filter 27 for separation of microorganisms so that the gas passage 25 communicates with the vent hole 26. This makes it easy to perform the transfer of the medical solution. In this case, it is preferred to provide a check valve 28, which allows the gas to flow only in the direction of the gas passage 25, adjacent to the filter 27 in the vent hole 26 on the inside of the filter 27, so as to prevent the medical solution from flowing into the vent hole 26 through the gas passage 25 when the vial is reversed. The check valve 28 is fixed in position by a stopper ring 29. A reference numeral 261 is a cap for closing a vent hole 26. It is not necessary to provide the cap if the check valve 28 is provided in the vent hole 26.

[0019] Use of the adapter for mixing and injection of preparations of the present invention will be explained below with reference to Fig. 7. The adapter for mixing and injection of preparations of the present invention is used under the condition where the tip C of the syringe S is fitted in the tip-fitting portion 3. Under such a condition, a vial (not illustrated) is fitted in the vial-fitting portion 1, thereby piercing the rubber stopper of the vial with the puncture needle 2 to communicate the syringe S with the vial. After this, a plunger rod P is pushed to transfer a solvent in the syringe S to the vial. The medicine in the vial is dissolved in the transferred solvent by shaking the vial to prepare a medical solution. The prepared medical solution in the vial can be sucked in the syringe S by pulling back the plunger rod P.

[0020] As will be understood from the above description, the use of the adapter of the present invention makes it possible to remove any foreign substances which are mixed in the medical solution during operation to dissolve the medicine in the solvent with the adapter for mixing and injection of preparations. Further, the adapter is simple in construction, thus making it possible to manufacture adapters for mixing and injection of preparations at a low price.

Claims

1. An adapter for mixing and injection of preparations comprising:

   a vial-fitting portion having a top wall and a skirt portion;
   a puncture needle passed through the top wall of the vial-fitting portion and integrated therewith, said puncture needle having a cutting edge on the side of said skirt; and
   a tubular tip-fitting portion located coaxially to the puncture needle on the opposite side thereof to the top wall,
   wherein said puncture needle has at a proximal end thereof a connecting portion for connection with the tip-fitting portion and a liquid passage which communicates with a lumen of the tip-fitting portion and is open to the cutting edge of the puncture needle, said connecting portion being provided at a liquid passage thereof with a filter.

2. The adapter for mixing and injection of preparations according to claim 1, wherein said puncture needle is provided with a gas passage which is open to the cutting edge, and wherein said connecting portion is provided with a vent hole with a filter for separation of microorganisms, said gas passage being communicated with the vent hole.

3. The adapter for mixing and injection of preparations according to claim 2, wherein said vent hole is provided with a check valve close to and inside of the filter, said check valve allowing the gas to flow only in the direction of the gas passage.

4. The adapter for mixing and injection of preparations according to any of claims 1 to 3, wherein said vial-fitting portion is provided at the skirt thereof with a longitudinal slit.

Fig. 1

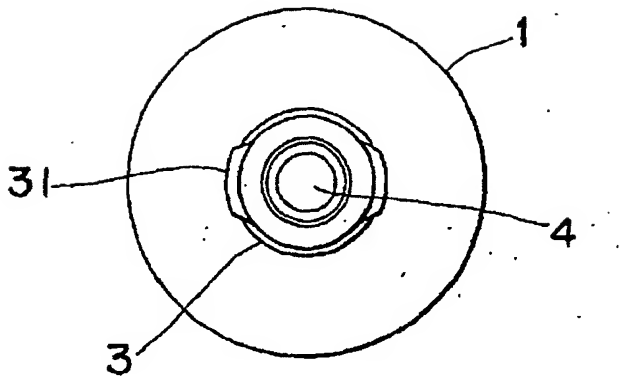


Fig. 2

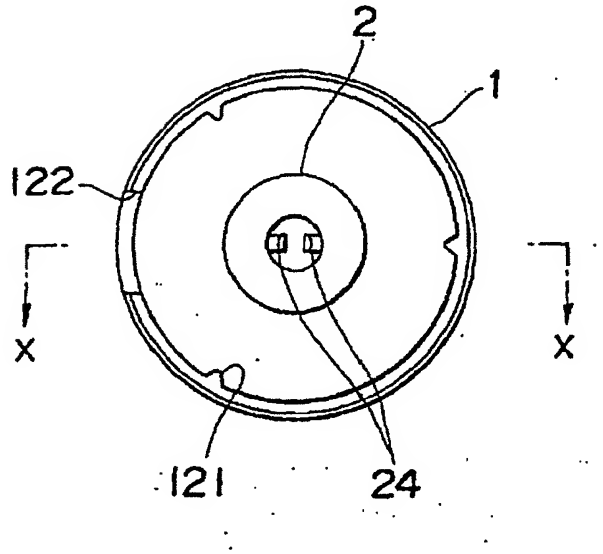


Fig. 3

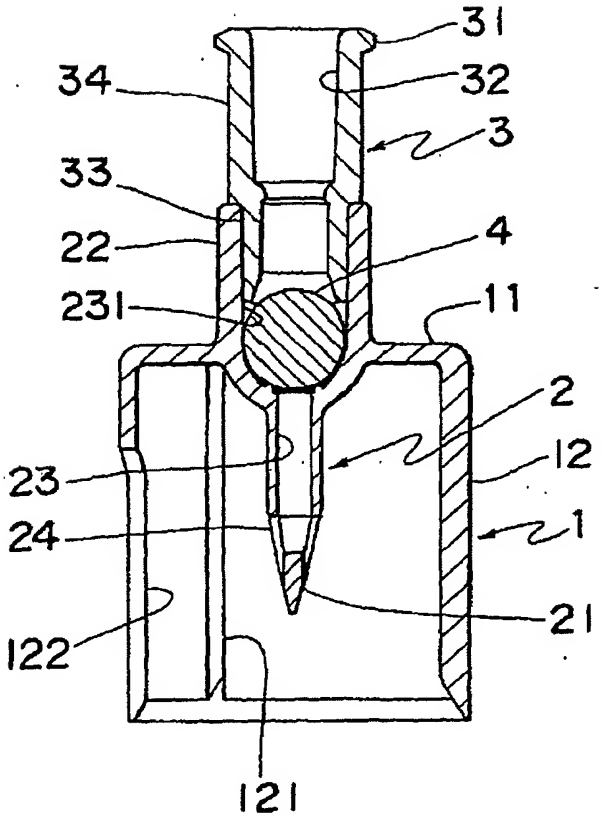


Fig. 4

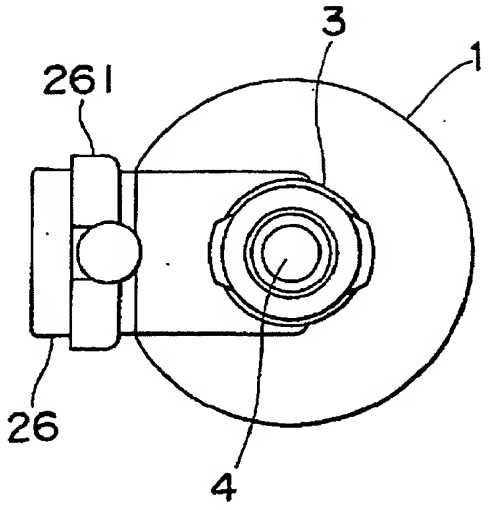


Fig. 5

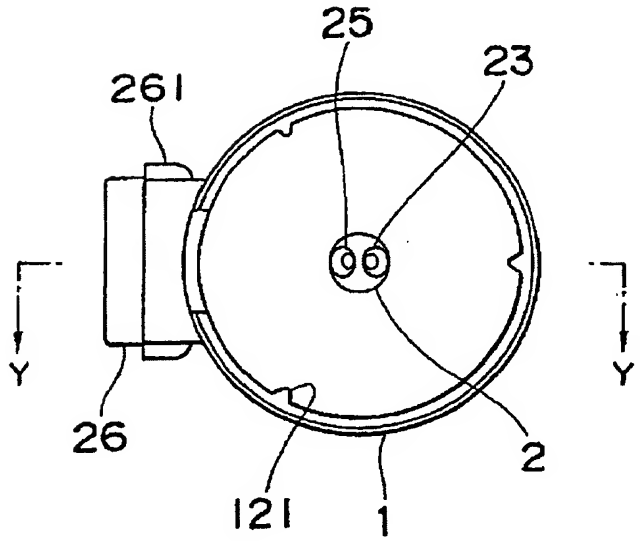


Fig.6

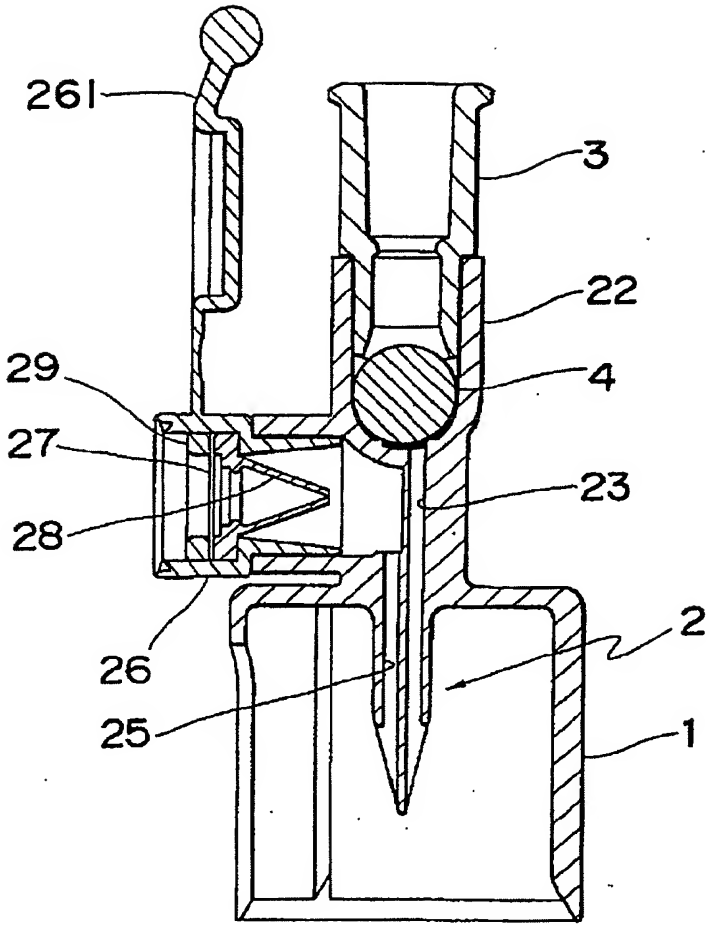
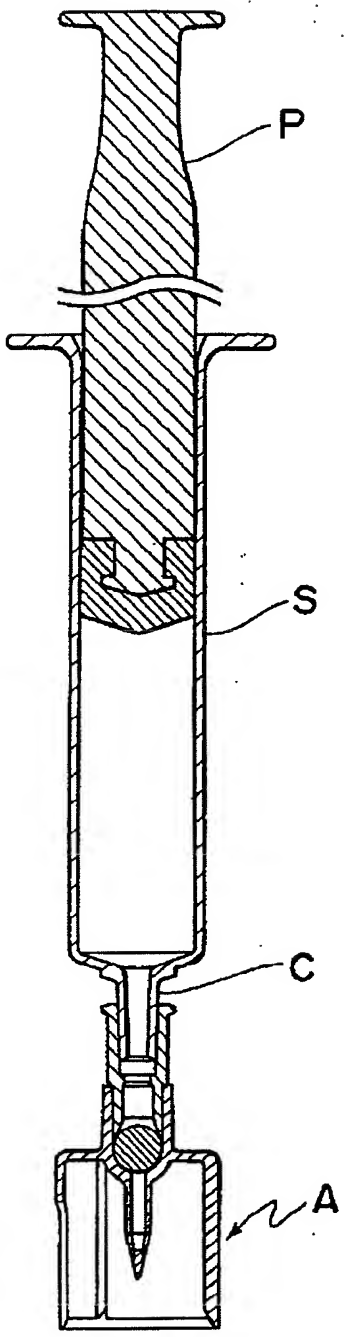


Fig. 7



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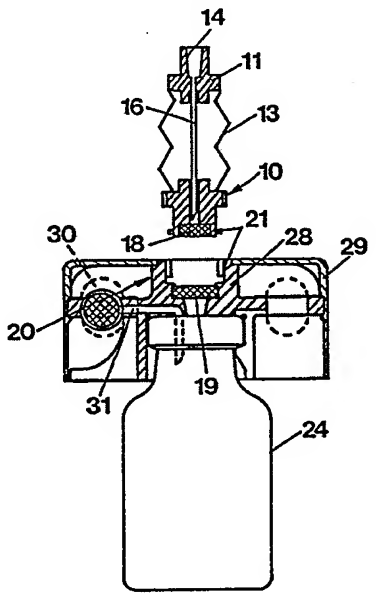
(54) A device for transferring a substance from one vessel to another and further to the intended application.

(57) A device for preventing air contamination when transferring a substance from a vessel (24) to a second vessel (10; 15) and further to the desired application, for example injection into a patient or other application. The device is attached or connectible to said vessel (24) and comprises a first member (10), in which a puncturing member (16), e.g. a needle provided with a passage is enclosed. The first member (10) has a sealing member (18), e.g. a membrane through which the needle can be passed. The device further comprises a second member (20), which is detachably connectable to the first member (20) and which also has a sealing member (19), e.g. a membrane. When the first and second members (10, 20) are connected to each other the two sealing members (18, 19) are located in a position with respect to each other so that they can be penetrated by the puncturing member (16), which is movable with respect to the sealing members (18, 19).



EP 0 126 718 A2

A DEVICE FOR TRANSFERRING A SUBSTANCE FROM ONE VESSEL TO ANOTHER AND FURTHER TO THE INTENDED APPLICATION

TECHNICAL FIELD

The present invention concerns a device for transferring a substance from a first vessel to a second vessel and further to the intended application and which device is attached or connectible to the said first vessel or a cover enclosing this and comprises a first member in which a puncturing member, e.g. a needle, providing with a passage is enclosed, and which first member has a sealing member, e.g. a membrane through which the puncturing member can be passed.

BACKGROUND OF THE INVENTION

On injection of a substance directly into a patient or via an infusion aggregate one cannot avoid contamination of the air through formation of aerosols or drops. This happens partly during drawing in the medium from the ampoule, in which it is normally contained, to the injection syringe, and partly in connection with the injection itself into the patient or the infusion bottle. This air contamination leads to problems among other things in the form of allergic reactions in the exposed personnel, especially when it is a question of cytotoxic drugs, anaesthetics, media containing isotopes and allergy inducing substances of various kinds.

The same problem with air contamination occurs during handling of poisonous chemicals, for example solvents of different types, in industries, in laboratories, etc.

There are previously known devices for transferring a medicine in liquid form from an ampoule to a bottle without contamination. Such an apparatus is shown for example in the Norwegian patent 141,537 and it contains a double needle, one end of which is protected by an elastic hood, which the needle

can penetrate by pressing together the hood, whereby the needle can be inserted into an ampoule. The opposite end of the needle is pushed through the membrane to a bottle with an infusion solution. This device presupposes that the medicine is already in the ampoule as a solution and therefore need not be dissolved first. Further there is no possibility of using the apparatus without contamination risk to inject the medicine directly into the patient.

PURPOSE OF THE INVENTION AND ITS MOST IMPORTANT FEATURES

The purpose of the present invention is to provide a device of the type previously mentioned and with which one can transfer without contamination a substance from a vessel to the desired application, for example injection into a patient or other application. This has been achieved by the fact that the apparatus further comprises a second member, to which said first member is detachably connectible and which also is provided with a second sealing member, e.g. a membrane, whereby the two sealing members in the connected position of the first and second members are located in a position with respect to each other, so that they can be penetrated by the puncturing member, which is movable relative to the sealing members.

DESCRIPTION OF THE DRAWING

In the following the invention will be described in detail with reference to some embodiments shown in the attached drawings.

Fig. 1 is a vertical section through a device according to the invention and an injection syringe and ampoule for connection to the device.

Fig. 2 is a corresponding section showing the device attached to the injection syringe and ampoule and in a postion where the needle is inserted into the ampoule.

Fig. 3 is a corresponding section but in a position where the first member of the device is uncoupled from the ampoule.

Fig. 4 is a section showing the first member of the device in position for coupling to a third member, which is attached to a cannula, vein catheter or the like.

Fig. 5 is a section through a modified variant of an ampoule equipped with a pressure equalization bladder and with a device according to the invention.

Fig 6 is section through an additional embodiment of the device attached to a large storage vessel containing for example a solvent.

Fig. 7-19 are sections through further embodiments of the device or parts thereof.

DESCRIPTION OF EMBODIMENTS

The device according to the embodiment shown in fig. 1-3 comprises two detachably coupled together members, of which the first 10 contains two plates 11 and 12 spaced from each other and which are connected through flexible side walls 13. On the first plate 11 there is provided an attachment piece 14 for an injection syringe 15. On the inside of the plate is further fastened a puncturing member in the form of a needle 16 with a passage, which communicates with the attachment piece 14. The other plate 12 has a passage for the needle 16, and a guide 17 for it. The needle 16 extends to said guide 17. A first membrane 18 is placed for apposition against the outside of the second plate 12.

The second member 20 of the device, which is connected to the first member 10 by a bayonet coupling 21, Luer lock coupling or the like contains a second membrane 19, which is placed in tight apposition against the first membrane 18. The membrane 19 is fastened in a ring shaped part 22, which on top is terminated by the coupling part to the first member 10 and on the bottom is terminated by an inwardly directed flange 23, so that part 20 can be snap fastened on an ampoule 24 containing a dry substance or a solution. The membranes 18 och 19 are appropriately made of Teflon^{R} -material, which seals itself tight after penetration. The membranes could also be provided with preformed holes, through which a puncturing member can

be passed. The tip of the puncturing member does in this case not need to be sharp.

By pressing together the flexible side walls 13 axially, as shown in fig. 2, the needle 16 penetrates the two membranes 18 and 19 and the rubber membrane 25 of the ampoule 24 and is inserted into the ampoule. If this contains a dry substance this can be dissolved by a solvent contained in the injection syringe and thereafter can be sucked up into the injection syringe. If the ampoule contains medicine in solution this is directly sucked up into the injection syringe 15.

When the substance has been sucked up into the injection syringe 15 the needle 16 is withdrawn through the membranes 18 and 19 and the second member 20 is allowed to remain on the ampoule 24 while the first member 10, which is attached to the injection syringe 15 is detached, as is shown in fig. 3. The second membrane 19 makes a tight seal to the ampoule 24 and is appropriately thrown away with it. The substance can now either be injected directly into a patient or be added into an infusion bottle. In order to avoid air contact also at this step a third member 32 (fig. 4) is arranged, one end of which is attached or connectible to the patient's cannula 26 or vein catheter or to the infusion bottle and the opposite end of which is connectible to the first member 10 in a corresponding way as the second member 20. If the substance is intended to be added to an infusion bottle the member 32 can be provided with a cannula, with which the membrane of the infusion bottle is penetrated, after which the first member 10 is connected. The third member also has a membrane 27 of the same type as the membranes 18 and 19. The membranes 18 and 27 are brought to tight apposition against each other when the members 10 and 32 are attached to each other. The needle 16 penetrates the membranes 18 and 27 by pressing together the flexible side walls 13 in the axial direction. When the injection is terminated the needle 16 is withdrawn through the membranes 18 and 27, which seal tightly again. The injection syringe 13 with the attached part 10 is then thrown away.

Air contact is avoided in this way completely from the transfer of the substance from the ampoule to the injection syringe and to injection into the patient or the infusion bottle.

In fig. 5 is shown a modified variant of the device according to the invention, where the second member 20 is integral with the closure means 28 of an ampoule 24. The membrane 19 is placed in an opening in the closure means 28, which also has a coupling means, for example an bayonet coupling 21, for the first member 10. The closure means 28 is covered by a hood 29 of metal, plastic or the like, under which is placed a torus-shaped expandable bladder 30, which via a tube or a needle 31 through the closure means 28 communicates with the interior of the ampoule 24. It would also be possible to provide the closure means 28 with a piece of tube (not shown) extending into the ampoule and through which the needle 16 can be passed. Said tube would be provided with a radial opening which via a passage through the stopper communicates with the bladder 30. A cylindrical bladder attachment with a liquid-rejecting filter is denoted with the numeral 32.

The bladder works as a pressure equalizer when handling the contents of the ampoule. If the ampoule contains a dry substance this must first be dissolved in a solvent, for example water, which is injected with an injection syringe. The air pushed out is then pressed into the bladder 30. To avoid liquid to enter the bladder 30 a filter can be placed between it and the tube or needle 31. On sucking up the dissolved substance into the injection syringe air is sucked back into the ampoule from the bladder 30. A completely closed pressure equalization system has thus been achieved. The bladder 30 can of course be arranged in other ways, for example as a balloon which hangs down below the hood 29, which in this case can be made smaller. I would also be possible to arrange a pressure equalizing bladder attached to the first member.

In fig. 6 is shown an embodiment designed for handling

poisonous chemicals, for example solvents, in laboratories, in industries etc. The first member 10 of the device is here attached to a large vessel 24 containing for example a solvent. The needle 16 extends into the container 24. When the solvent is to be taken out of the vessel 24 the second member 20 of the device is connected to a second vessel, whereupon the members 10 and 20 are coupled together and the flexible side walls 13 are pressed together so that the needle 16 penetrates the membranes 18 and 19.

In fig. 7 is shown an embodiment, in which the first member 10 comprises a pair of telescoping parts, the outer 33 of which having e needle 16 attached thereto and being arranged to receive an injection syringe 15. The inner part 34 is provided with a first membrane 18 at its end facing away from the outer part 33 and is arranged to be coupled together with the second member 20 of the device, e.g. in a corresponding manner as is shown in fig. 5 by means of a bayonet coupling 21 or the like. The telescoping parts 33 and 34 are each provided with stop lugs 35 preventing the parts from being separated from each other. At the end portions facing each other the telescoping parts 33 and 34 are fluted 36 in the axial direction for preventing the parts from being rotated relative to each other in the most extended position. The injection syringe 15 is firmly locked to the outer part 33 by means of a disc 37 of e.g. metal attached to said part and provided with a central slotted opening with sharp edges and into which the conical connection piece 38 is passed, at which the the material portions between the slots will be bent upwards as seen in fig. 7. An attempt to withdraw the injection syringe 15 from the part 33 will result in that the sharp edges surrounding the opening in the disc 37 will be pressed into the walls of the connection piece 38 and a withdrawal is effectively prevented. A lip sealing 39 is attached to the inner part 34 and which seals between the interior of the inner part 34 and the outer part 33. Air is admitted to pass between the telescoping parts 33 and 34 as is indicated with arrows in fig. 7. The second member of the device can e.g. be of the kind shown in fig. 5.

In fig. 8 is shown a further embodiment, in which the needle 16 is displaceably received in the first member 10 and sealed against this by a sealing 40. The needle is provided with a ventilated piston guide 33, which is guided against the inside of the first member 10, which in this case is designed as a cylinder. The needle 16 is fixed to a connection piece 42, to which the injection syringe 15 can be undetachably connected in the corresponding way as in the embodiment according to fig. 7. The second member 20 of the device can e.g. be of the kind shown in fig. 5.

In fig. 9a-b is shown how the device can be applied on substances delivered in sealed ampoules 43. These are at the neck provided with a weakening 44, at which it easily can be broken off by hand. The unbroken ampoule 43 is placed in a bag or casing 45 of a pliable, strong and preferably transparent material and which after that is closed by a seal 46 (fig. 9a). The ampoule is broken at the weakening 44 when located in the bag 45. The bag 45 is provided with a connection member corresponding to the second member 20 and to which the first member 10 can be connected. The ampoule is moved in the bag 45 so that its opening will be located just opposite and connected to the second member 20, while its broken-off end 47 remains beside the ampoule (fig. 9b). Alternatively the bag 45 is only provided with a connection member to which the second member 20 can be coupled. The transfer of the substance from the ampoule 43 to e.g. an injection syringe connected to the first member 10 is performed in exactly the same way as is described above by bringing the needle 16 to penetrate the membranes 18 and 19 and be inserted into the ampoule 43.

In fig. 10 is shown a modified embodiment according to which the needle 16 is closed at the tip and provided with a radial opening 48 communicating with the passage of the needle. The first member 10 comprises a sealing member 18 in the form of a sleeve through which the needle 16 passes and which seals the opening 48 when the needle is in the position shown in fig. 10. The second member 20 is attached to the ampoule 24 and has

a bayonet coupling 21 for receiving the first member 10 in a position where the sleeve-shaped membrane 18 lies tight against the membrane 19. The needle 16 is passed through the sleeve 18 and membrane 25 and into the ampoule 24 by pressing together the flexible side walls 13 of the first member 10. The mobility of the needle 16 with respect to the sleeve 18 and membrane 19 can of course be achieved in other ways too.

In the embodiment shown in fig. 11 the first member comprises two parts 49,50 threaded into each other, the needle 16 being attached to the outer part 49 and the first membrane 18 to the inner part 50. Said inner part 50 is further provided with coupling means in the form of gripping arms 51 intended to grip about the bottle-neck of the first vessel 24. In this case the first membrane 18 makes a unit with a resilient stopper 52 at the free end of said inner part 50. When the first member 10 is coupled to the vessel 24 the first membrane 18 is pressed against the closure means of the vessel 24. The membrane 25 of the vessel makes said second membrane. The first membrane 18 has a convex sealing surface in order to inprove the sealing effect against the closure means of the vessel 24.

The needle 16 is provided with a radial opening 53, which in a certain position of the needle when this has penetrated the membranes 18 and 25 is closed by a sealing 54 in the first member and through which the needle passes. Preferably, the needle 16 cannot be moved past said position. The substance in the vessel 24 can now be transferred through the needle 16 e.g. to an injection syringe. For ventilating or pressure equalizing the vessel 24 the needle is withdrawn a certain distance so that the radial opening 53 is exposed and admits the interior of the vessel 24 to communicate with the interior of the member 10. This is provided with a ventilating hole 55 covered by a liquid-rejecting filter 56. An expandable bladder (not shown) could of course be arranged to communicate with said hole 55 in order to provide a closed pressure-equalizing system.

In the embodiment shown in fig. 12 the first member 10 also makes the second vessel to which the substance is transferred. The needle 16 is provided with a piston guide 74 having a passage 57 connecting the interior of the member 10 with the passage of the needle 16. The piston guide 74 is further provided with a nonreturn valve 58, so that the it can be moved downwards towards the membrane 18. When moving the piston guide 74 and the needle 16 in the opposite direction a suction effect is provided in the member 10 at which the substance is sucked into the member 10 through the needle 16 and passage 57. The member can then be disconnected from the second member 20 and the substance be transferred to the intended application via a third member 32 (fig. 4).

In this embodiment the second member 20 is provided with a pointed member 61 for penetrating the closure means (membrane 25) of the vessel 24. The pointed member 61 has a passage 62 through which the needle 16 can be passed and which further communicates with a ventilating passage 59 in the second member 20. Said ventilating passage is covered by a liquid-rejecting filter 60. The pointed member 61 is preferably made as an integral unit with the second member 20 of a plastic material.

The embodiment of fig. 13 differs from the one according to fig. 13 through the design of the pointed member 61. This is provided with two passages one 62 for the needle 16 and the other 63 for ventilating the vessel 24. The inlet openings of the two passages are located so far from each other that the risk for sucking air into the neddle 16 is eliminated.

In the embodiment shown in fig. 14 the second member 20 is provided with a ventilating passage 59 covered by a liquid-rejecting filter 60. Connection means 73 are provided on the member 20 for connecting a resilient bladder 30 or tube to the member 20 over the filter 60. If there are no poisonous vapours in the system the device could be used without bladder 30, which could be supplied as a separate unit and connected to the member 20 when substances with poisonous vapours are to

be transferred.

The pointed member 61 could make the coupling means for coupling the device 10,20 to the vessel 24 as is shown in fig.15. In this case the pointed member 61 is provided with outwardly directed projections, e.g. barbs 64 for making the coupling safe.

In cases where the membrane of the vessel 24 makes the second membrane a pointed member 61 connecting the first member 10 to the second member could be provided with a line of weakness. For disconnecting the two members the pointed member 54 is simply broken off and sealed by being bent or otherwise squeezed together.

In the embodiment of fig. 16 there are two puncturing members or needles 16 and 64 attached to the first member 10 and which both penetrate the membranes 18 and 19. The telescoping parts 33,34 of the member 10 are unrotatably connected to each other. The second needle 64 comprises an open slotted needle or has a through passage with radial holes for providing a connection between the interior volume of the vessel 24 and the atmosphere via the filter 60 or to an expandable bladder covering this. The interior of the first member 10 could possibly also be ventilated through said second needle 64. The second membrane 19 in this embodiment has a convex contact surface for improving the sealing effect against the membrane of the vessel 24, which in this case makes the second membrane.

In fig. 17 is shown a further embodiment wherein the first member 10 is in one piece with the second vessel 15, the piston of which is given the numeral 65. The member 10 comprises two parts 49 and 50 threaded into each other. The needle 16 is over portion near its free end surrounded by a further needle 66 attached to the needle and having a cutting edge at a angle to the cutting edge of the needle 16. Said angle preferably corresponds to the pitch of the threads of the treated members 49,50 as the needles 16 and 66 are rotated

through the membranes 18 and 25. The space between the two needles 16 and 66 admits ventilation of the vessel 24.

The gripping arms 51 for coupling the member 10 to the bottle-neck of the vessel 24 are pressed against this by tightening a nut 67.

In fig. 18 is shown a further variant of a needle 16 designed for being passed through the membranes by rotation. The needle 16 is at its end portion helical 68 and a second helical needle 69 is wound about said helical portion 68. The second helical needle 69 is provided with a through passage for ventilating the vessel 24. The pitch of the helical portion 68 and member 69 preferably corresponds to the pitch of the threads of the portions 49,50 of the first member 10.

In fig. 19 is shown a further embodiment in which the needle 16 is passed through a piston 70 slidingly received in the member 10, which also makes the second vessel to which the substance is transferred. The piston rod 71 is designed as a semi-cylindrical member, so that it is possible to manoeuvre the needle 16 from within said piston rod 71. A radial opening 72 is provided in the needle 16.

It would be possible to make the device without a needle, whereby the device is equipped with a membrane at the end remote from the membranes 18 and through which a needle from an injection syringe can be passed. The device then functions in the same way as described above.

Several variants of the device according to the invention are of course possible within the scope of the claims. It would be possible to make the needle 16 displaceable in the device with a lever on its outside provided with an air sealing. The needle is then sealed against and guided by the inside of the first member by means of a piston guide or a collar portion.

In most of the embodiments shown the membranes 18 and 19 or 25 are brought to tight apposition against each other in the

connected position of the members 10 and 20. This gives a sealing effect between a membranes and eliminates the risk for any leakage of the substance between the membranes. In some embodiments there is shown a certain distance between the membranes in the connected position of the members 10 and 20, which does not give the above sealing effect, but the risk for leakage between the membranes is small.

Other orientations of the membranes 18 and 19, 25 with respect to each other are of course possible within the scope of the claims. They need not to be located just opposite each other, the purpose is that they can be penetrated by the needle.

A plurality of modifications are possible and it should be pointed out that portions from the different embodiments can be replaced and combined with each other in many ways.

CLAIMS

1. A device for transferring a substance from a first vessel (24;43) to a second vessel (10;15) and further to the intended application and which device is attached or connectible to the said first vessel or a cover (45) enclosing this and comprises a first member (10) in which a puncturing member (16), e.g. a needle, provided with a passage is enclosed, and which first member has a sealing member (18), e.g. a membrane through which the puncturing member (16) can be passed,
c h a r a c t e r i z e d i n,
that said device further comprising a second member (20), to which said first member (10) is detachably connectible and which is provided with a second sealing member (19), e.g. a membrane, whereby the two sealing members (18,19;25) in the connected position of the first and second members (10,20) are located in a position with respect to each other, so that they can be penetrated by the puncturing member (16), which is movable relative to the sealing members (18,19;25).

2. A device according to claim 1,
c h a r a c t e r i z e d i n,
that said sealing members (18,19;25) in the connected position of the first and second members (10,20) are brought to tight apposition against each other.

3. A device according to claim 1 or 2,
c h a r a c t e r i z e d i n,
that said second member (20) makes a unit with the closure means (25,28) of said first vessel (24).

4. A device according to any of claims 1-3,
c h a r a c t e r i z e d i n,
that said first member (10) is so designed that the distance between the first sealing member (18) and the attachement for the puncturing member (16) can be lengthened and shortened.

5. A device according to claim 4,

c h a r a c t e r i z e d i n,
that the first member (10) has flexible side walls (13) whereby through pressing the walls together in the axial direction of the puncturing member (16), this is caused to pass through the sealing members (18,19;25).

6. A device according to claim 5,
c h a r a c t e r i z e d i n,
that the puncturing member (16) is displacably arranged in the first member (10) and guided along the inside thereof.

7. A device according to claim 6,
c h a r a c t e r i z e d i n,
that the first member (10) comprises a cylinder and the puncturing member (16) being provided with a ventilated piston guide (41) slidingly received within said cylinder, the puncturing member being attached to a connection piece (42) arranged to firmly receive said second vessel (15), e.g. an injection syringe and a sealing (40) being arranged to seal between the puncturing member and the interior of said cylinder.

8. A device according to claim 5,
c h a r a c t e r i z e d i n,
that the first member (10) comprises a pair of telescoping parts (33,34) the puncturing member (16) being attached to one part and the first sealing member (18) being attached to the other part.

9. A device according to claim 8,
c h a r a c t e r i z e d i n,
that the outer telescoping part (33) comprises means for firmly receiving said second vessel (15), e.g. an injection syringe the puncturing member (16) being attached to said outer part and said first sealing member (18) being attached to the inner part (34), a sealing (39) being provided to seal between the interior of the inner part and the outer part and air being admitted to pass between the inside of the outer part and the outside of the inner part, said inner and outer

parts being undetachably and unrotatably connected to each other at least in the most extended position.

10. A device according to claim 5,
c h a r a c t e r i z e d i n,
that the first member (10) comprises a pair of parts (49,50) threaded into each other, the puncturing member (16) being attached to one part and the first sealing member (18) being attached to the other part.

11. A device according to claim 5,
c h a r a c t e r i z e d i n,
that the puncturing member (16) is displaceably arranged in the first member (10) by a lever manouverable from the outside thereof.

12. A device according to any of the preceding claims,
c h a r a c t e r i z e d i n,
that said first sealing member (18) is in the form of a sleeve through which the puncturing member (16) is passed and which in one position is arranged to cover a radial opening (48) in the needle communicating with the transmission channel thereof, the tip of the needle being closed and the needle being movable with respect to said sealing member (18) to a position where the radial opening is exposed.

13. A device according to any of claims 1-12,
c h a r a c t e r i z e d i n,
that the puncturing member (16) is provided with a radial opening (53), so that the interior of the first vessel (24) can communicate with the interior of the first member (10) in a certain position of the puncturing member (16), and that a sealing (54) is provided for closing said radial opening in a second certain position of the puncturing member.

14. A device according to any of the preceding claims,
c h a r a c t e r i z e d i n,
that the passage of the puncturing member (16) is arranged to communicate with the interior volume of said first member

(10) which make said second vessel.

15. A device according to any of the preceding claims, c h a r a c t e r i z e d i n, that the device comprises a third member (32) one end of which is attached or connectible to a cannula, a vein catheter an infusion bottle or the like and the opposite end of which is connectible to the first member (10), and which is provided with a puncturable sealing member (27), e.g. a membrane arranged to be located in a position with respect to the first sealing member (18), so that these can be penetrated by the puncturing member (16) and preferably are located to tight apposition against each other when the third and first members are in the connected position.

16. A device according to any of the preceding claims, c h a r a c t e r i z e d i n, that the device is provided with coupling means (23;51) arranged to be connected to said first vessel (24) about the bottle-neck therof.

17. A device as claimed in any of claims 1-15, c h a r a c t e r i z e d i n, that the device is provided with coupling means (21;) arranged to be connected to said first vessel (24) in a cavity in the closure means (29) thereof.

18. A device according to any of the preceding claims, c h a r a c t e r i z e d i n, that an expandable bladder (30) is arranged to communicate with the interior of the first vessel (24) for pressure equalization when transferring the substance.

19. A device according to any of the preceding claims, c h a r a c t e r i z e d i n, that said device is provided with a pointed member (61) having a passage (62) therethrough and which can be passed through the closure means of the first vessel (24), at which the puncturing member (16) is arranged to be passed through said

pointed member into the first vessel.

20. A device according to claim 19,
c h a r a c t e r i z e d i n,
said pointed member (61) has a passage (62;63) communicating with the atmosphere via a liquid-rejecting filter (60) or with an expandable bladder (30) for ventilating the first vessel(24).

21. A device according to any of claims 18 -20,
c h a r a c t e r i z e d i n,
that said pointed member (61) makes the coupling means for connecting the device to said first vessel (24).

22. A device according to any of claims 1-18,
c h a r a c t e r i z e d i n,
that two substantially parallel puncturing members (16,64) are arranged to both be passed through the first and second sealing members, one of said puncturing members (16) being arranged to transfer the substance to said second vessel (10;15) and the second (64) being provided with a passage for ventilating the interior of the first vessel when said second puncturing member is passed through the second sealing member (19;25).

23. A device according to claim 22,
c h a r a c t e r i z e d i n,
that said passage of said second puncturing member (64) also is arranged to ventilate the interior of the first member (10).

24. A device according to any of claims 1-18,
c h a r a c t e r i z e d i n,
that the puncturing member (16) over a portion near its free end is surrounded by a further puncturing member (66) attached to the first puncturing member (16), at which there is a free space between the two puncturing members arranged to ventilate the interior of the first vessel (24).

25. A device according to claim 10,
c h a r a c t e r i z e d i n,
that the puncturing member (16) has a helical end portion (68), a second helical puncturing member (69) being wound about said end portion, said second helical puncturing member having a passage therethrough arranged to ventilate the interior of the first vessel (24).

26. A device according to claim 25,
c h a r a c t e r i z e d i n,
the pitch of said helical portion (68) and member (69) corresponds to the pith of thread of the threaded portions (49,50) of the first member (10).

27. A device according to any of the preceding claims,
c h a r a c t e r i z e d i n,
that the first sealing member (18) has a convex sealing surface.

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FIG 1

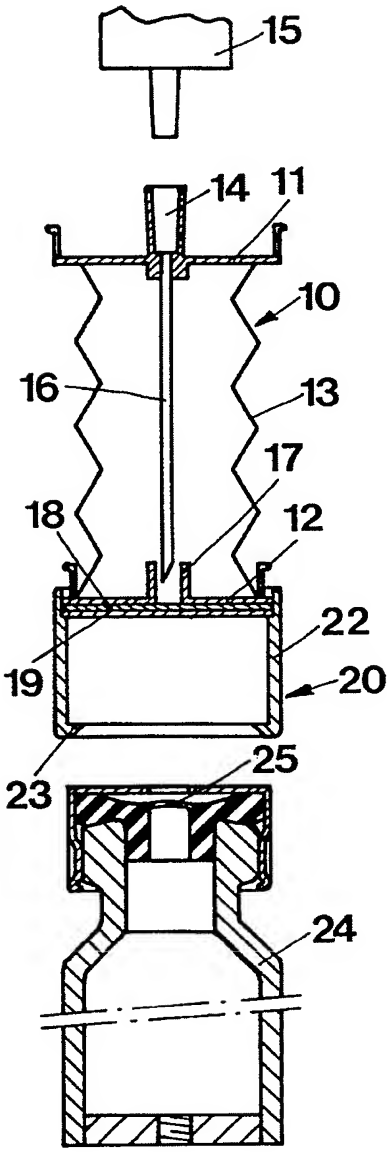

FIG 2

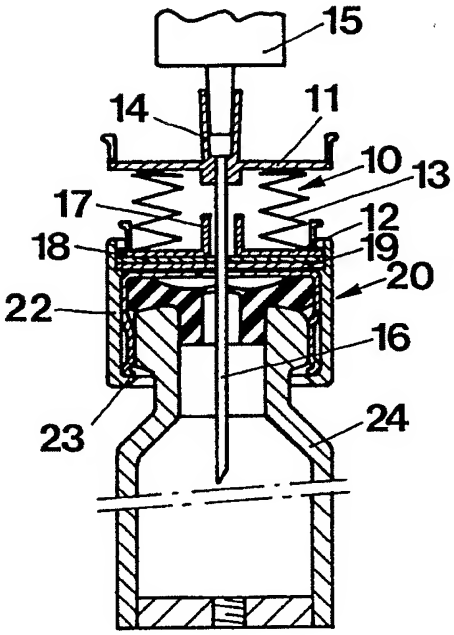

FIG 3

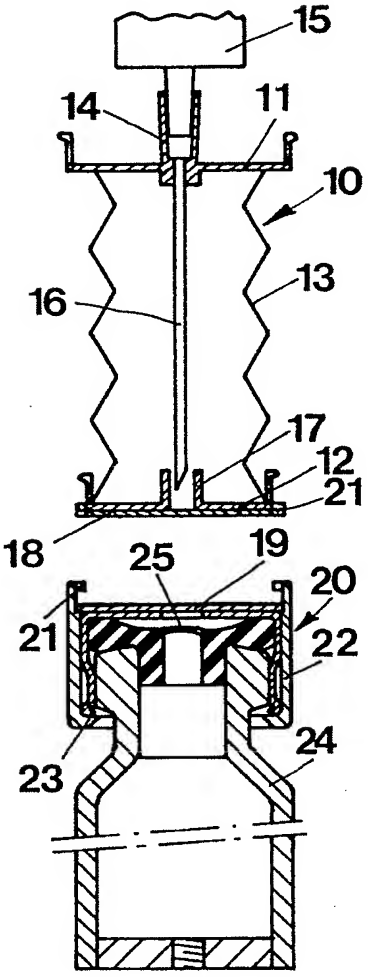

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FIG 4

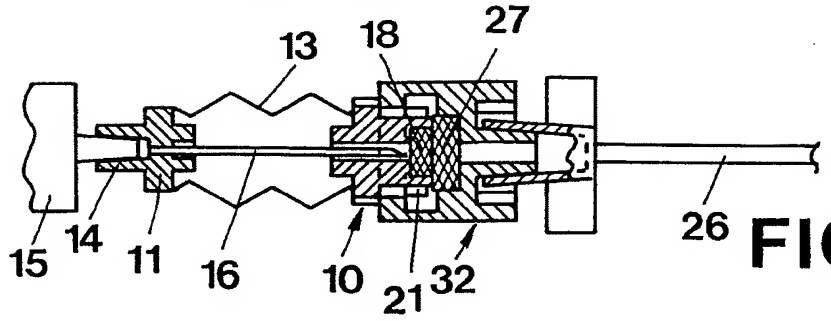

FIG 5

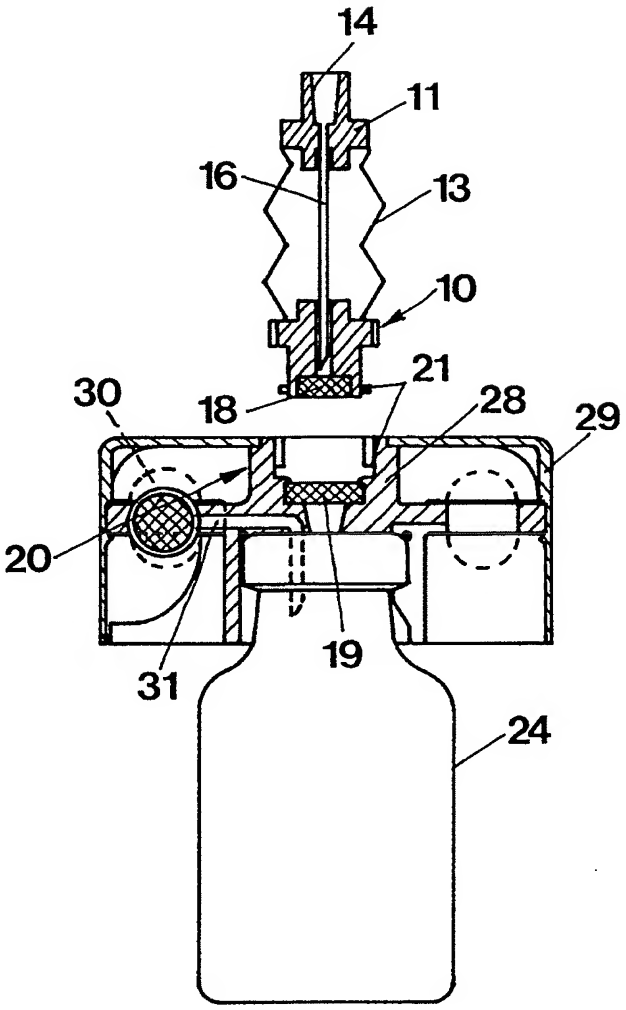

FIG 6

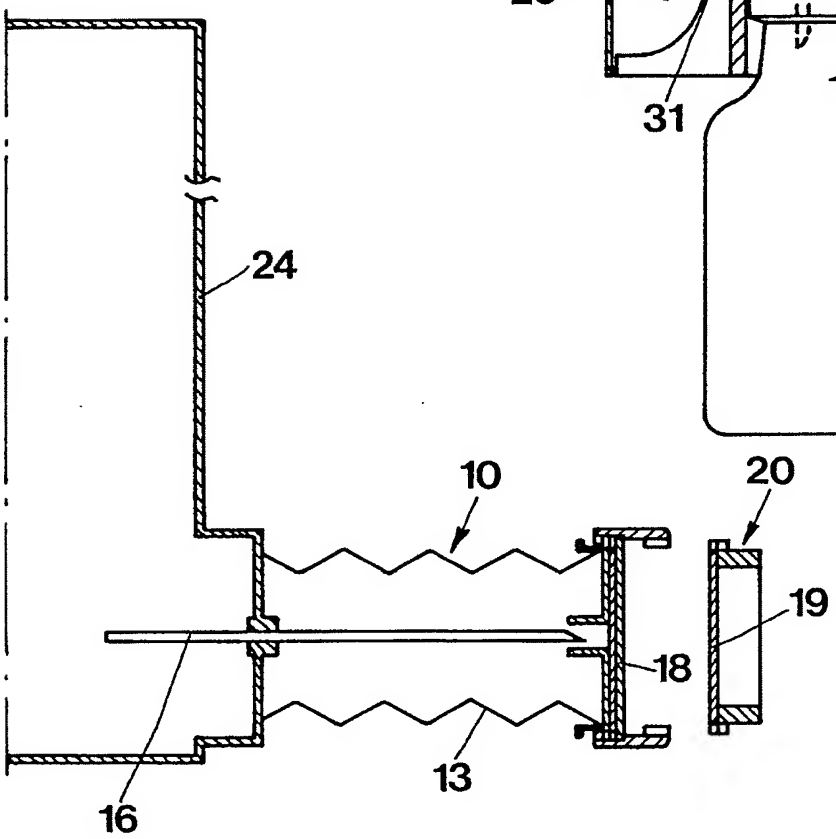

FIG 7

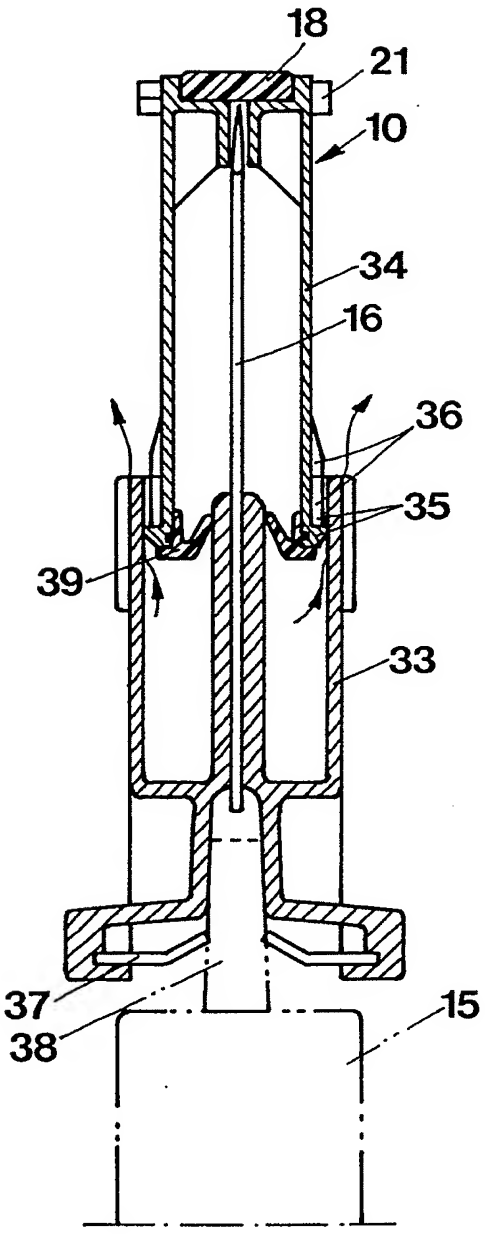

FIG 9a

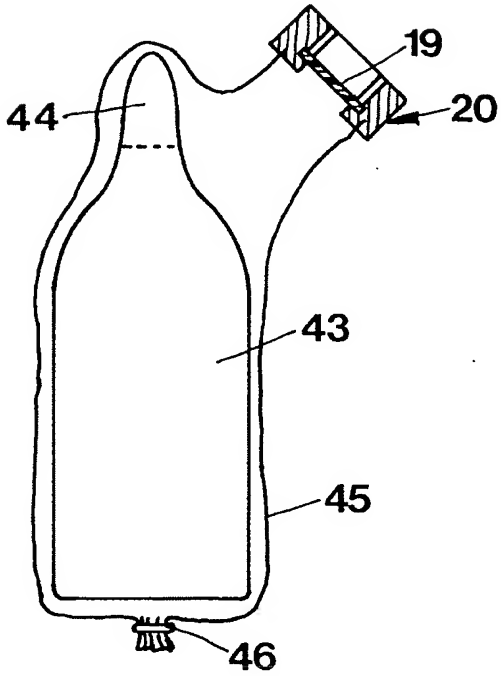

FIG 9b

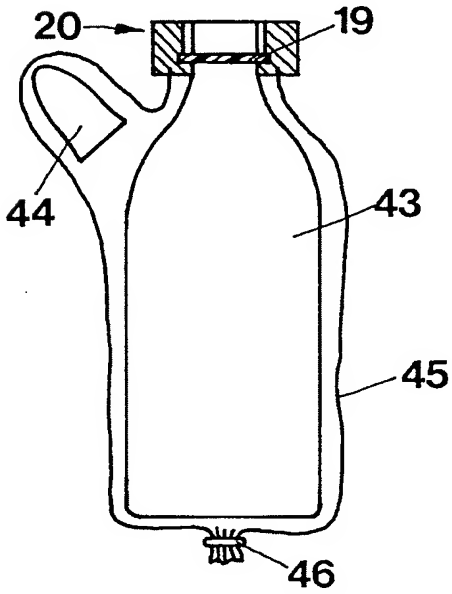

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FIG 8

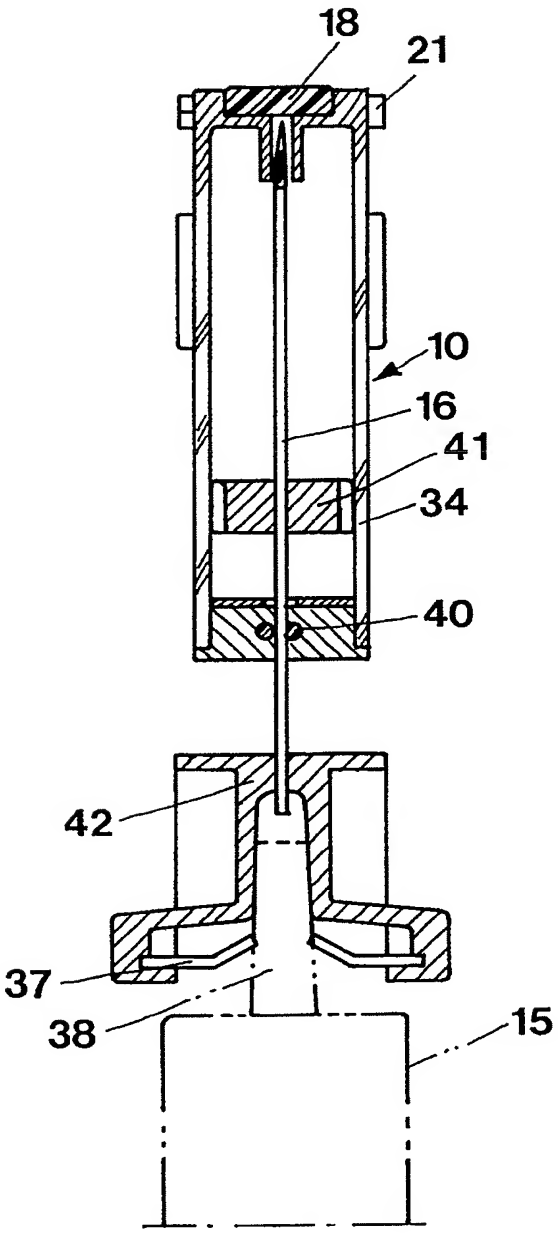

FIG 10

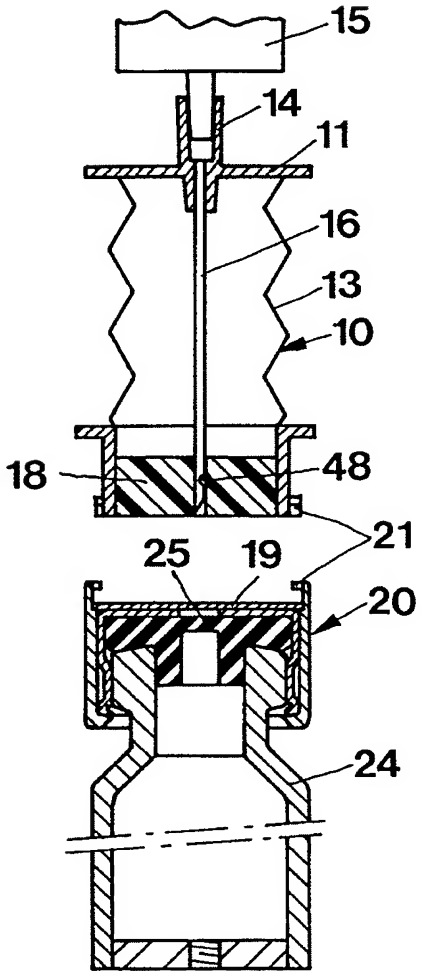

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FIG 11

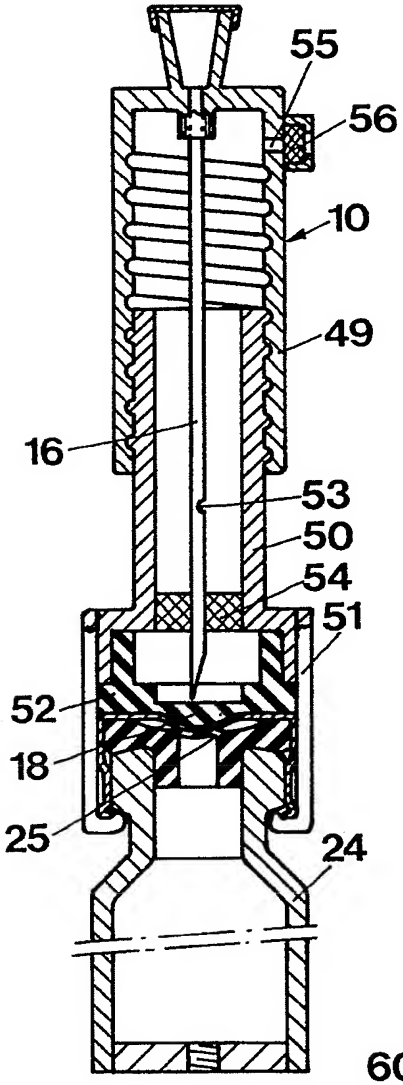

FIG 12

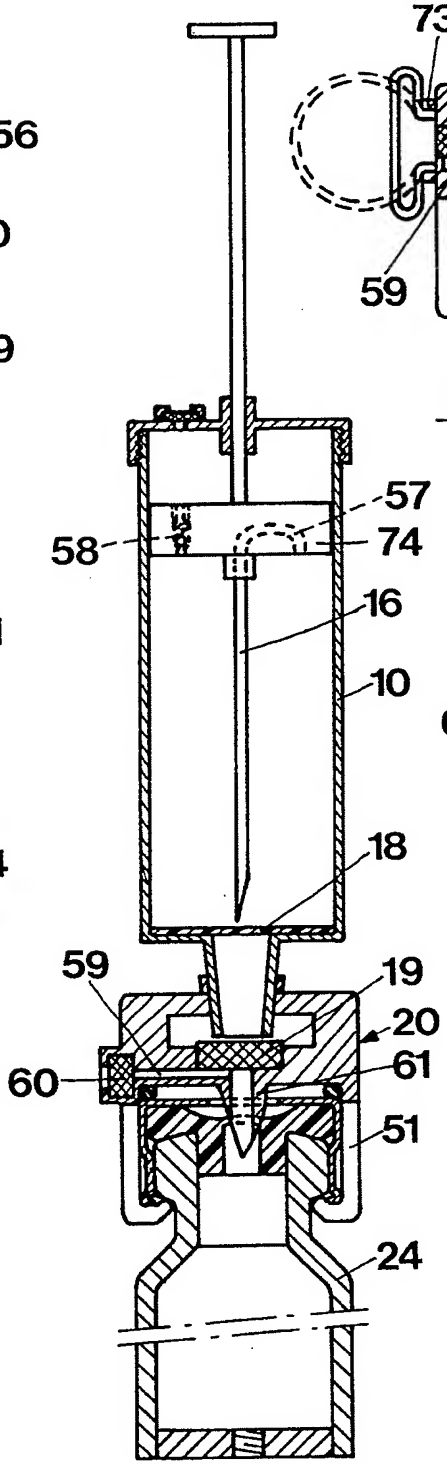

FIG 14

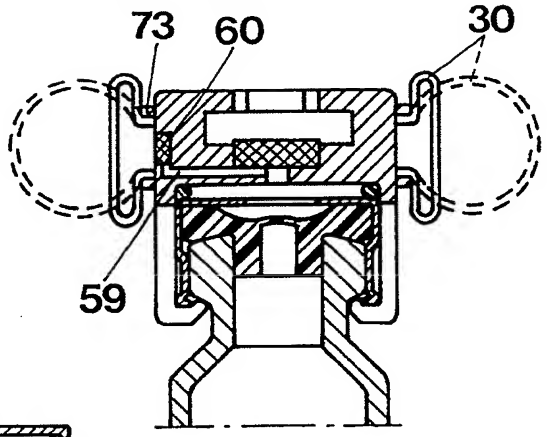

FIG 13

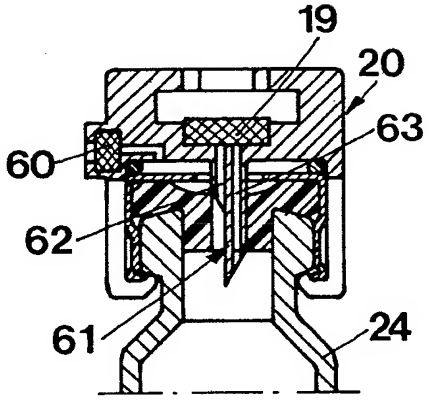

FIG 15

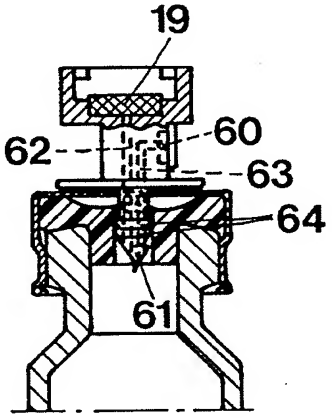

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FIG 16

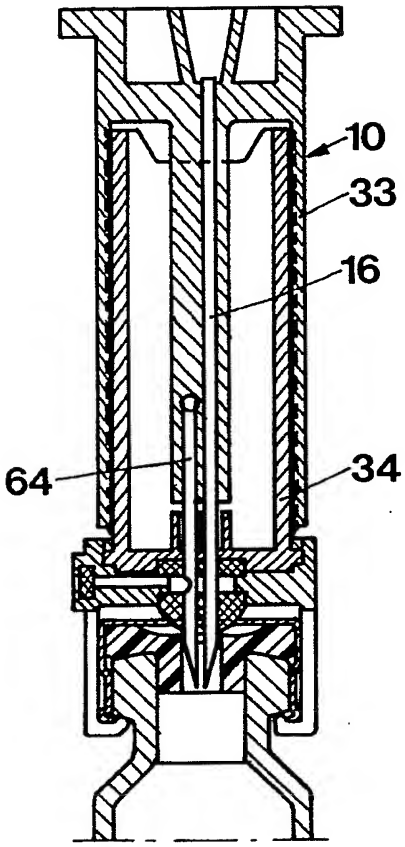


FIG 17

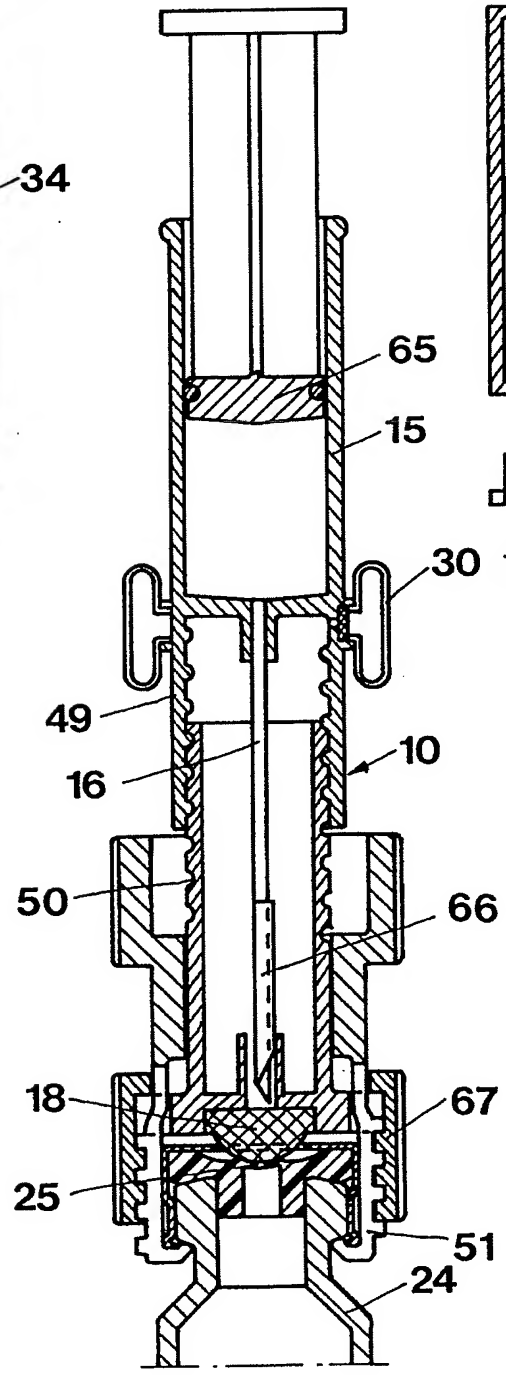


FIG 19

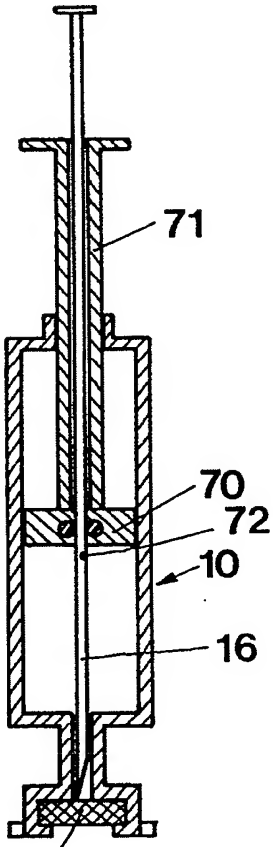
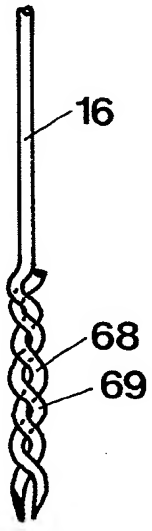


FIG 18



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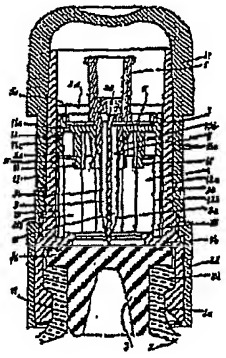
[54]发明名称 尤其位于带可穿孔塞子的容器和注射器之间的连接装置

[57]摘要

在第一容器(2)和包括套筒接头(4a)的第二容器(4)之间的连接装置(1),它包括一个塞子穿孔装置(5),一方面有一个套筒接管(6),另一方面有一个通过过滤器(8)与外部隔开的过滤室(7),在穿孔装置(5)内有两个独立的通道(9,10),使第一容器(2)的内部与套筒接管(6)和过滤室(7)分别相通,该装置另外还包括带有穿孔装置(5)导向机构的移动装置(11),将套圈(12)固定在颈部(2a)上的紧固装置(13),安装在内孔(12a)内的活塞(15),上面固定着通过简单推进而滑动的穿孔装置(5),以及活塞(15)的最终止动装置(16)。



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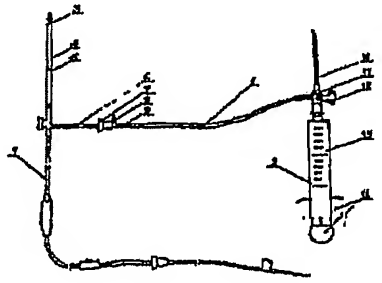
权利要求书 1 页 说明书 4 页 附图页数 2 页

[54]实用新型名称 带加药器的防污染一次性输液器

[57]摘要

本实用新型涉及一种带加药器的防污染一次性输液器，它包括输液器 1 及与其上部以栓、孔形式插合联接的加药器 2，其特征在于：加药器 2 由注射器 13 与其前端安装的具有侧孔柱 11 的三通阀门针头 10，侧孔柱 11 设有远端为孔栓 9 装置的加药管 6，具有相当长度的输液器 1 瓶针 4 下端配有带过滤器 7 和具备阻塞盖的插口 8 装置的加药管 6 结构组成。本技术具有结构简单，体积小，性能可靠，防止污染，使用灵活方便，工作效率高，集溶药、加药及临时给药为一体，成本低廉等特点。



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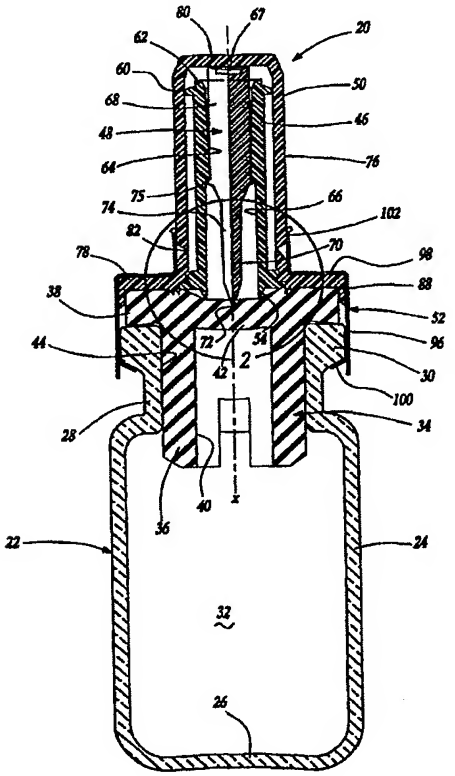
(54) Title: VIAL TRANSFERSET AND METHOD

(57) Abstract

This invention relates to an improved vial transfer assembly or vial transferset which may be attached to a vial under sterile conditions and used to transfer fluid to or from a conventional vial. The transferset includes a tubular transfer member which is sealingly supported on the rim portion of a vial stopper, a piercing member having a piercing end reciprocally supported by an internal surface of the transfer member, a cap enclosing the tubular transfer member and a collar preferably formed of a malleable material which secures the assembly on the stopper, which is crimped beneath the vial rim. The piercing member has a generally longitudinal external channel which, upon piercing the planar portion of the stopper, establishes fluid communication with the vial through the tubular transfer member. The distal end of the tubular transfer member includes a Luer lock for establishing fluid communication to a syringe, IV set or the like. An annular lip on the proximate end of the tubular transfer member stretches and prestresses the central portion of the planar stopper rim and the piercing member is supported in the transferset such that the piercing end deforms the prestressed stopper rim portion.



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VIAL TRANSFERSET AND METHOD

FIELD OF THE INVENTION

This invention relates to an improved vial connector assembly or transferset, a method of affixing a transferset to a vial and a method of establishing fluid communication between a vial and syringe, IV set or the like which permits the use of a conventional or standard vial and syringe or the like to transfer fluid from a syringe to a vial or withdraw liquid medicament, for example, from a vial to a syringe. The improved transferset and method of this invention results in improved aspiration or reaspiration of a vial and improved sealing of the communication between a vial and a syringe.

BACKGROUND OF THE INVENTION

It is now conventional to reduce certain drugs to a dry or powdered form to increase the shelf life of drugs and reduce inventory space. Such dry or powdered drugs are generally stored in a sealed vial and reconstituted into liquid form for administration to a patient by adding a diluent or solvent. A conventional vial includes an open end, a rim surrounding the open end and a reduced diameter neck portion adjacent the rim. The vial is conventionally sealed with an elastomeric stopper which includes a portion inserted into the neck of the vial and a planar rim portion which overlies the vial rim. The stopper is normally secured to the vial rim with an aluminum collar or cap. The aluminum collar includes a tubular portion which surrounds the rim portions of the stopper and vial, an inwardly projecting annular portion which overlies the rim portion of the stopper and a distal portion which is crimped into the vial neck beneath the vial rim portion. Because aluminum is malleable, the collar accommodates the buildup of tolerances of the dimensions of the stopper and vial rim. The dimensions and tolerances of standard vials and stoppers are set by the International Standards Organization (ISO).

A powdered drug is generally reconstituted by inserting the needle of a syringe through the pierceable stopper on the vial and injecting a diluent, such as water, or a solvent into the vial. The reconstituted drug is then reaspirated from the vial with the same or a different syringe after mixing the diluent or solvent with the dry drug. As will be understood, this method exposes the healthcare worker to being pricked by the needle of the syringe and contamination of the needle or the drug.

The prior art has therefore proposed various fluid or liquid transfer assemblies which may be secured to a vial under sterile conditions and which may then utilized to transfer liquid, such as a diluent or solvent, from a syringe to a vial and reconstituted medicament from the vial to a syringe which prevent contamination of the liquid medicament. In the most preferred embodiments, the assembly is protected from contamination by a cap or cover which is removed only prior to use. In the embodiments disclosed in the prior art, the transfer assembly includes a needle which pierces the stopper of the vial and the liquid is transferred through the needle lumen as disclosed, for example, in U.S. Patent No. 5,429,256. In other embodiments, the conventional vial stopper is eliminated in favor of a fluid transfer assembly having a rubber stopper which is inserted into the neck of the vial without a planar rim portion. The stopper remains within the vial until such time as reconstitution of the drug is required. When the transfer assembly is actuated, the stopper is urged toward the interior of the vial to open the neck, thereby permitting fluid flow through the transfer assembly into the vial body. Examples of such embodiments include the MONOVIAL® line of drug delivery devices manufactured and sold by Becton Dickinson Pharmaceutical Systems of Le Pont de Claix, France and exemplified by U.S. Patent No. 5,358,501. Although this embodiment is an excellent drug reconstitution system having superior properties, particularly convenience of use and maintenance of the sterile conditions of the drug in the vial, particularly where the vial is of a relatively large size, typically twelve milliliters or more,

pharmaceutical companies have expressed an interest in an approach where the vial may also be a smaller size.

The need therefore remains for a vial transferset which may be utilized with an ISO standard vial and stopper to transfer liquid from a conventional syringe to the vial or from a vial to a syringe after reconstituting a drug, for example, which is relatively simple in design and which reduces or eliminates contamination of the drug. It would also be desirable to eliminate the use of a conventional syringe needle to pierce the elastomeric stopper which seals the vial. As will be understood by those skilled in the art, a conventional syringe needle is thin and has an internal axial lumen or bore. The needle must therefore be withdrawn during aspiration of the vial or reaspiration where the medicament is reconstituted in the vial following delivery of a diluent or solvent to the vial. Where the needle is not substantially completely withdrawn during reaspiration of the vial, liquid medicament remains in the vial because the only liquid communication with the syringe is through the needle lumen. This may be a problem particularly where the vial is relatively small. For example, assuming a twenty millimeter long needle which pierces a two to three millimeter thick stopper, if the needle is pushed all the way through the stopper, there may be distance of as much as seventeen millimeters between the needle opening and the inner surface of the stopper. This amount below the needle lumen will not be reaspirated unless the needle is substantially withdrawn.

The vial transferset and method of this invention solves these problems by providing a relatively simple and efficient fluid transfer assembly which may be affixed to an ISO standard vial which assures complete reaspiration of the vial and which does not require accurate positioning of the needle during reaspiration.

SUMMARY OF THE INVENTION

The vial transferset or fluid transfer assembly of this invention is adapted to establish fluid communication between a syringe, intravenous (IV)

device or the like and a sealed vial. As set forth above, the syringe and vial may be conventional and manufactured according to ISO standards. A conventional vial as presently used by the pharmaceutical companies includes an open end, a rim surrounding the open end and a reduced diameter neck portion adjacent the rim. The vial is sealed with a pierceable resilient stopper generally formed of an elastomeric material and most commonly includes a portion which is inserted into the neck of the vial and a planar rim portion which is received over the vial rim. The central portion of the planar rim portion which overlies the opening through the neck portion of the vial generally has a thickness of about two to three millimeters and the portion of the stopper which is received in the neck portion of the vial is generally tubular having an external diameter which is slightly greater than the internal diameter of the vial neck portion to assure a secure seal.

The transferset or transfer assembly of this invention includes a generally tubular transfer member having an open proximate end which is sealingly supported on the stopper rim portion for example in general coaxial alignment with the vial open end and an opened distal end adapted to receive a syringe or the like in sealed communication. As used in this application, the proximate end of a component such as the tubular transfer member is the end closest to the planar rim portion of the stopper and the distal end is the end furthest from the rim portion of the stopper. As will be understood, these terms are used solely to simplify the explanation of the invention and are not intended to define structure.

The transferset of this invention further includes a piercing member which is received within the tubular transfer member and reciprocally supported within the tubular transfer member by an internal surface of the tubular transfer member. The piercing member includes a relatively sharp preferably pointed piercing proximate end opposite the stopper rim portion adapted to pierce the stopper and an opposed distal end. As discussed more fully hereinbelow, the tubular transfer member provides fluid communication between the vial and a syringe, although the vial transferset of this invention

may also be used to transfer fluid or liquid from a vial to another container, such as a second vial or an intravenous set. In the most preferred embodiment of the transferset of this invention, the piercing member includes at least one external generally longitudinal channel or groove rather than an internal lumen, thereby eliminating the problems associated with a conventional needle. Although the channel may take various forms and may include an internal channel, in the most preferred embodiment the channel is an external channel which extends generally longitudinally along at least a portion of the piercing member. As will be understood, the external channel in the piercing member extends generally longitudinally along the piercing member, but may extend spirally around the piercing member or include external and internal channels or multiple channels. Thus, when the piercing member is driven through the rim portion of the stopper, the external channel in the piercing member provides full fluid or liquid communication between the vial and the tubular transfer member. Of course, when the tubular transfer member is sealingly connected to a syringe, IV or the like, the tubular transfer member then provides fluid communication between the vial and the syringe. The preferred embodiment of the tubular transfer member then includes an annular or circular projecting sealing lip which is biased against the planar rim portion of the stopper assuring sealed communication between the vial and the tubular transfer member. In the most preferred embodiment, the sealing lip includes a relatively sharp edge which bites into the resilient stopper. As discussed more fully hereinbelow, the sealing lip of the tubular transfer member is preferably biased against the rim portion of the stopper sufficiently to stretch or prestress the rim portion of the stopper which overlies the vial opening.

The preferred embodiment of the transferset of this invention further includes a cup-shaped cap which encloses the assembly and maintains the sterility of the transferset assembly. The cup-shaped cap preferably includes a radial rim portion adjacent an open end of the cup-shaped cap which preferably sealingly engages the stopper rim portion, a tubular portion

surrounding the tubular transfer member and a closed distal end enclosing the distal ends of the tubular transfer member and the piercing member. Although the cap may include a separate cover portion which is integral or separate from the remainder of the cap, in the most preferred embodiment, the cap is integrally formed, such that the distal end portion may be removed prior to use. In the disclosed embodiment, the tubular portion of the cap spaced from the rim portion includes a radial groove or grooves which weaken the tubular wall forming a frangible connection. The distal end of the cap portion may then be removed simply by twisting the distal end of the cap, thereby breaking the frangible connection.

The transfer assembly is secured to the vial by a generally tubular collar having a radially inwardly projecting portion or annular portion which is received over the cap radial rim portion, a tubular portion surrounding the cap radial rim portion and the vial rim and a distal radial rim portion which is received in the vial neck beneath the rim portion of the vial permanently securing the transfer assembly to the vial. In the most preferred embodiment of the transferset of this invention, the collar is formed of a malleable material such aluminum and the radial distal portion of the collar is then crimped into the neck portion of the vial beneath the vial rim portion. The collar of the transferset of this invention thus replaces the aluminum collar of a conventional vial and stopper assembly and easily accommodates the dimensional tolerances of the vial and stopper assembly. The vial is conventionally formed of glass or plastic.

As described above, the planar radial rim portion of the vial stopper is preferably stretched and prestressed over the open end of the vial during assembly of the transferset on the vial. The proximate end of the tubular transfer member includes a projecting sealing lip having a diameter less than the internal diameter of the vial open end. In one preferred embodiment, the sealing lip has a relatively sharp edge which may also bite into the resilient stopper. In the most preferred embodiment, the piercing member is reciprocally supported by an internal surface of the tubular transfer member,

such that the piercing member can move toward the stopper to pierce the stopper, but the piercing member is prevented from moving away from the stopper and the relatively sharp piercing proximate end of the piercing member extends beyond the proximate end of the tubular transfer member. Upon assembly of the transferset on the vial, the piercing end of the piercing member then deforms and, in one disclosed embodiment, partially penetrates the planar rim portion of the stopper which is preferably stretched and prestressed over the vial opening by the sealing lip of the tubular transfer member, as described above. This combination may reduce the force required for the piercing member to fully pierce the planar rim portion of the stopper upon activation which is another advantage of the present invention. In another disclosed embodiment, the piercing end of the piercing member is slightly rounded and the external channel does not extend through the proximate end, such that the relatively sharp piercing end does not initially penetrate the rim portion of the stopper, but stretches the stopper as described. This embodiment strengthens the piercing end. Further, deforming the stopper planar rim portion and stretching the planar portion over the open end of the vial, reduces the volume of elastomeric material deformed into the V-shaped groove or external channel in the piercing member following piercing of the stopper, thereby improving fluid flow through the channel. In the disclosed embodiment, the tubular transfer member includes an internal diameter adjacent its distal end which is smaller than the internal diameter adjacent its proximate end and the piercing member includes a radial lip having a diameter greater than the smaller internal diameter of the tubular transfer member adjacent its distal end. Stated another way, the tubular transfer member has a larger counter bore adjacent its proximate end. The piercing member is thus free to move telescopically in the tubular transfer member toward the stopper, but prevented from moving away from the stopper. In the most preferred embodiment, the piercing member has a reduced diameter portion adjacent its proximate end and a

pointed piercing end further reducing the force required to drive the piercing member through the planar rim portion of the stopper.

The most preferred embodiment of the transferset of this invention further includes a second seal surrounding the seal provided by the sealing lip of the tubular transfer member. In this preferred embodiment, the second seal is provided by an annular or circular lip which projects from the radial rim portion of the cap. In the most preferred embodiment, the radial rim portion of the cap includes at least one relatively sharp sealing lip which bites into the planar rim portion of the stopper providing an improved seal which maintains the sterile condition of the content of the transferset and prevents contamination.

As described above, the transferset of this invention may be affixed on a conventional vial and stopper assembly by the pharmaceutical companies under sterile conditions when the vial is filled and the transferset of this invention prevents contamination of the contents of the vial. The cap of the transferset seals the transfer assembly and the collar permanently secures the assembly on the vial, particularly where a malleable collar is utilized. The radially inwardly projecting or annular lip portion of the collar is preferably compressed against the radial rim portion of the cap as the distal end of the collar is crimped into the reduced diameter neck portion of the vial beneath the vial rim during assembly. This compression against the resilient planar rim portion of the stopper compresses the sealing lips of the cap and the tubular transfer member against the rim portion of the stopper, such that the sealing lips bite into the rim portion of the stopper assuring sealed communication between the stopper and the tubular transfer member. In the most preferred embodiment, the piercing end of the piercing member is also partially driven into the prestressed rim portion of the stopper overlying the open end of the vial, reducing the stroke required to drive the piercing member through the rim portion of the stopper as described above.

The method of assembling the improved transferset of this invention on a vial then includes inserting the elongated piercing member into the

tubular transfer member, wherein the internal surface of the tubular transfer member telescopically supports the piercing member. Where the tubular transfer member includes an enlarged counterbore adjacent its proximate end and the piercing member includes a radial lip as described, the distal end of the piercing member is inserted through the proximate end of the tubular transfer member and the relatively sharp piercing end of the piercing member extends beyond the proximate end of the tubular transfer member. The method then includes inserting the distal end of the tubular transfer member into the open proximate end of the cup-shaped cap. In the most preferred embodiment of the transferset, the proximate end of the tubular transfer member includes a radial lip portion which is received within a counterbore of the radial rim portion of the cap, fixing the tubular transfer member in the cap, such that the projecting sealing lip of the tubular transfer member engages the planar rim of the stopper as described. Further, the piercing member is preferably releasably retained in the tubular transfer member, such that the components of the transferset and the collar may be preassembled and delivered in bulk to a pharmaceutical company, for example, for sterile assembly on vials. Finally, the assembled piercing member, tubular transfer member and cap are assembled on the vial and affixed by the collar. As described, the collar is most preferably formed of a malleable material such as aluminum and the radial rim portion of the collar is compressed against the rim portion of the cap as the distal end of the generally tubular cap is crimped into the reduced diameter neck portion of the vial beneath the vial rim. The compression of the radial rim portion of the collar against the rim portion of the cap compresses the resilient planar rim portion of the stopper, compressing the sealing lips into the rim portion of the stopper, stretching and pre-stressing the central portion of the planar rim portion of the stopper, assuring sealed communication between the vial and the tubular transfer member. In the most preferred embodiment, the method of this invention further includes driving the piercing end of the piercing member simultaneously into the planar radial rim of the stopper, deforming and may

partially penetrate the stopper radial rim to reduce the stroke required to drive the piercing member through the stopper.

The method of transferring fluid or liquid medicament from the vial to a syringe or other container then includes first removing the cover portion of the cap to provide access to the tubular transfer member and the piercing member. In the most preferred embodiment, a radial groove is provided in the tubular portion of the cap spaced from the radial portion of the cap providing a frangible connection, such that the cover portion can be removed from the rim portion of the cap simply by twisting the distal end of the cap, breaking the frangible connection and permitting removal of the cover portion which includes the distal end of the tubular portion of the cap the closed end.

The transferset and vial assembly is now ready for use. As set forth above, the transferset of this invention may be utilized to transfer fluid from a vial to a syringe or IV set or any container; however, the disclosed embodiment of the transferset is specifically adapted to transfer liquid from a vial to a syringe or IV set or from a syringe or IV set to a vial. The distal end of the tubular transfer member includes a connector adapted to connect the tubular transfer member to a syringe to establish fluid communication between the tubular transfer member and the interior of a syringe, such as a Luer lock or Luer connector. A conventional syringe includes a tubular portion, a plunger having a head or fluid piston reciprocally mounted in sealed relation within the tubular portion and a reduced diameter tubular nozzle portion opposite the plunger head. The inside diameter of the tubular transfer member of the transferset is preferably greater than the outside diameter of the tubular nozzle portion of the syringe and the outside diameter of the syringe nozzle portion is generally approximately equal to the diameter of the distal end of the piercing member. Thus, the syringe nozzle portion may be telescopically received within the distal end of the tubular transfer member, wherein it is driven against the distal end of the piercing member. The reduced diameter nozzle portion is generally recessed within the tubular portion of the syringe, such that the proximate end of the syringe tubular

portion surrounds the nozzle portion forming a tubular collar. The proximate end of the tubular collar includes a connector, such as a female Luer lock. In the disclosed embodiment, the distal end of the tubular transfer member includes a male Luer lock connector adapted to mate with the female Luer lock of the syringe.

Following removal of the cover portion of the cap as described above, the connector on the syringe is connected to the connector on the distal end of the tubular transfer member which drives the reduced diameter nozzle portion of the syringe into the distal open end of the tubular transfer member and the free end of the syringe nozzle portion is then driven against the distal end of the piercing member, driving the piercing end of the piercing member through the planar rim portion of the stopper. In summary, the method includes connecting the syringe to the distal end of the tubular transfer member, establishing fluid communication between the syringe through the nozzle portion and driving the piercing end of the piercing member through the rim portion of the stopper. Fluid communication is thus established between the inside of the vial and the syringe through the tubular transfer member.

In the most preferred embodiment of the transferset of this invention, wherein the piercing member includes an external generally longitudinal channel, this communication is established through the external generally longitudinal channel in the piercing member. In the most preferred embodiment, the channel in the piercing member extends from adjacent the piercing end to at least the enlarged portion of the piercing member and most preferably through at least an extended portion of the length of the piercing member. The connector on the syringe is most preferably a threaded connection, such as a Luer lock. In one embodiment, this threaded connection has several turns whereby the proximate end of the piercing member is driven completely through the planar rim portion of the stopper by threading the threaded connection of the syringe on the distal end of the tubular transfer member. In another embodiment, the proximate end of the

piercing member is driven through the stopper by fluid pressure from the syringe.

As will now be understood, the piercing member in the transferset of this invention has several important advantages over the prior art. First, the piercing member is easy to manufacture. The longitudinal channel may be a V-shaped channel for example which extends the entire length of the piercing member. Such a channel is easier to manufacture than a needle having very small lumen as presently used. More importantly, in the transferset of this invention, a piercing member having an external channel assures complete aspiration or reaspiration of the vial without requiring partial withdrawal of the needle which exposes the healthcare worker to being pricked by the needle (if inadvertently fully withdrawn) and contamination of the liquid medicament. The external channel provides full communication of the liquid content of the vial, whereas a needle with a lumen requires substantial withdrawal of the needle from the vial to provide full communication through the stopper as described above. Fluid communication between the syringe and the vial is then provided by the tubular transfer member rather than the needle in the transferset of this invention. Thus, the described piercing member provides several important advantages in the transferset of this invention over the prior art.

As described, the transferset of this invention may be utilized to reconstitute dry or powdered drugs into liquid form with an appropriate diluent or solvent solution prior to administration to a patient. For example, the syringe may contain a solvent solution or diluent which is injected into the vial through the tubular transfer member and the external channel of the piercing member by depressing the plunger head of the syringe. The reconstituted drug or medicament may then be reaspirated from the vial to the same syringe by withdrawing the plunger head for administration to a patient. The healthcare worker is never exposed to a needle during this operation and the piercing member remains with the transferset and vial assembly because it is never connected to the syringe. The tubular transfer member is then

removed from the syringe and replaced with a needle for application of the liquid medicament to a patient or connected directly to an IV line.

As will be understood, the terms tubular and tubular portion are used herein to connote a generally tubular shape. Although the disclosed embodiments are generally cylindrical tubes which are more convenient to manufacture, the tubular portions may be of any convenient shape, including polygonal. Other advantages and meritorious features of the present invention will be more fully understood from the following description of the preferred embodiments, the claims and the appended drawings, a brief description of which follows.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a side cross-sectional view of an assembled vial and fluid transfer assembly or transferset;

Figure 2 is an enlarged view of the encircled portion 2 shown in Figure 1;

Figure 3 is a partial side cross-sectional view of the vial and transferset assembly shown in Figure 1 with the cover portion of the transferset removed;

Figure 4 is a partial cross-sectional view of the vial and transferset assembly as shown in Figure 3 with a syringe oriented for connection to the transferset;

Figure 5 is a partial side cross-sectional view of the vial and transferset assembly with the syringe ready for connection to the transferset;

Figure 6 is a partial side cross-sectional view of the vial, transferset and syringe with the syringe connected to the transferset and the plunger of the syringe moved to transmit liquid from the syringe to the vial;

Figure 7 is an enlarged side-cross sectional view of Figure 6 illustrating the fluid communication between the vial and the transferset;

Figure 8 is a top cross-sectional view of Figure 6 in the direction of view arrows 8-8;

Figure 9 is an exploded side elevation of the vial, transferset and syringe;

Figure 10 is an exploded side view of the transferset, vial and stopper prior to assembly;

Figure 11 is an enlarged side-cross sectional view of a second embodiment of a transferset and vial assembly;

Figure 12 is a side cross-sectional view of the vial and transferset of Figure 11 illustrating piercing of the vial stopper;

Figure 13 is a partial side cross-sectional view of the vial and transfer set of Figures 11 and 12 illustrating the flow of fluid from the syringe to the vial;

Figure 14 is a perspective view of the piercing member utilized in the transferset shown in Figures 11 to 13;

Figure 15 is an enlarged view of the encircled portion 15 of Figure 13;

Figure 16 is a side partially cross-sectioned view of an alternative preferred embodiment of the transferset of this invention;

Figure 17 is a side elevation of the piercing member shown in Figure 16; and

Figure 18 is an enlarged fragmentary side cross-sectional view of Figure 16 illustrating the interconnection between the tubular transfer member and the cap of this embodiment.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

As described above, the fluid transfer assembly or transferset 20 of this invention is adapted for establishing fluid communication with a conventional sealed vial 22 as shown in Figure 1. The vial includes a side wall portion 24, a bottom wall portion 26, a reduced diameter neck portion 28 and a rim portion 30. The vial is conventionally formed of glass or plastic and includes an interior 32 for receipt for example of a dry or liquid medicament, such as a dry vaccine 33. The vial is sealed with an elastomeric stopper 34 which includes a tubular portion 36 and a planar rim portion 38.

The tubular portion 36 of the stopper preferably has an external diameter slightly greater than the internal diameter 44 of the open end of the vial and, as will be understood by those skilled in the art, the end of the tubular portion may include axial slots 40 in order to perform freeze drying of liquid in the vial. As will be understood, the vial may also include a gas, for example, to protect the liquid content of the vial, and thus the transferset of this invention is referred to as a fluid, rather than liquid transferset. The central portion 42 of the planar rim portion 38 is flexible and thus may be resiliently biased into the tubular portion 36, prestressing the central portion 42 as described below.

The transferset 20 of this invention preferably includes four components, including a tubular transfer member 46, a central piercing member 48 which is reciprocally supported in the tubular transfer member, a cup-shaped cap 50 which encloses and seals the assembly and a collar member 52 which secures the transferset to the vial as shown in Figure 1. The proximate end of the tubular transfer member 46 includes a circular or annular sealing lip 54 as shown in Figures 1 and 2, which preferably includes a sharp distal edge 56 as shown in Figure 2. As will be understood, the proximate end of the tubular transfer member 46 may include a plurality of sealing lips, such as the concentric sealing lips 86 of the cap 50 described below. In the disclosed embodiment, the proximate end of the tubular transfer member 46 further includes a radial connector portion 58 as shown in Figure 2 which is described more fully hereinbelow. A connector, such as a Luer lock 60, is provided adjacent the open distal end 62 of the tubular transfer member. The internal surface of the tubular transfer member 46 includes a first smaller preferably conical diameter 64 adjacent the distal end 62 and a second larger generally cylindrical diameter 66 or counterbore adjacent the proximate end.

The distal end 67 of the piercing member 48 includes a generally cylindrical barrel portion 68 having an external diameter generally equal to or slightly less than the internal diameter 64 of the tubular transfer member 46, such that the piercing member is telescopically supported in the tubular

transfer member 46 for movement toward the stopper 34 as described below. The piercing portion 70 adjacent the proximate end of the piercing member 48 may also be generally cylindrical and preferably has a diameter substantially less than the diameter of the barrel portion 68. In the disclosed embodiment, the portion 73 of the piercing member between the radial rib 75 and the barrel portion 68 is conical. The proximate end of the piercing member 48 includes a relatively sharp, preferably pointed piercing end 72 and the piercing member 48 includes an external generally longitudinal channel 74 which provides communication between the interior 32 of the vial and the interior of the tubular transfer member 46 as described below.

The piercing member 48 further includes a radial rib 75 which has a diameter greater than the inside diameter 64 of the tubular transfer member 46 adjacent its distal end and slightly smaller than the inside diameter 66 of the counter-bore, such that the piercing member 48 can move toward the planar radial rim portion 38 of the stopper for piercing of the stopper, but cannot move away from the stopper as shown in Figure 1. In the preferred embodiment of the transferset of this invention, the sharp piercing end 72 of the piercing member 48 is thus retained in the tubular transfer member 46, such that the relatively sharp piercing end portion 72 of the piercing member deforms the central portion 42 of the stopper and may partially penetrate the stopper as shown, thereby reducing the stroke required to drive the piercing member through the stopper as described below.

The cap 50 includes a tubular portion 76 which surrounds the tubular transfer member 46 preferably is spaced relation, a radial rim portion 78 at its proximate end and a closed distal end portion 80 which encloses the distal ends of the tubular transfer member 62 and the piercing member 67. The cap 50 is thus generally described as "cup-shaped"; however, the cap may have an open distal end which is closed by a separate removable closure, for example, such that the combination is cup-shaped. The tubular portion 76 of the cap includes a radial v-shaped external groove 82, such that the proximate end of the tubular portion 76 is retained to the distal portion by a relatively

thin frangible connection 84 as shown in Figure 2. The groove 82 in the disclosed embodiment of the tubular portion 76 of the cap 50 is in the external surface as shown; however the groove may also be formed in the internal surface forming a frangible connection adjacent the external surface. The groove 82, whether internal or external, may also be continuous as shown or interrupted. Alternatively, the cover portion may be connected to the remainder of the cap by spaced frangible connector portions. As described below, the distal portion of the cap or cover portion may then be removed by twisting the distal end of the cap for connection of the transferset to a syringe or the like. In the preferred embodiment of the transferset, the radial rim portion 78 includes annular or preferably circular concentric sealing lips 86 which surround the sealing lip 54 of the tubular transfer member. As shown in Figure 2, the circular lips 86 on the radial portion 78 of the cap surround the sealing lip 54 on the tubular transfer member, providing a safety seal primarily to maintain sterility inside the cap 50 prior to use, thereby extending the shelf life of the product. Although the disclosed embodiment includes two concentric sealing lips 86 on the cap, it will be understood that one sealing lip may be utilized or a plurality of nonconcentric lips. The sealing lips 86 preferably have a relatively sharp edge and are V-shaped, such that the lips 86 bite into the resilient planar rim portion 38 of the stopper.

The disclosed embodiment of the cap 50 further includes an outer longitudinal rim portion 88 having an inside diameter generally equal to or slightly smaller than the outside diameter of the planar rim portion 38 of the stopper as shown in Figure 1, such that the transferset 20 is accurately located on the stopper 34 and the rim portion 30 of the vial 22 with the tubular transfer member 46 generally coaxially aligned with the opening 44 through the neck portion 28 of the vial. In the disclosed embodiment, the piercing member 48 is supported in the tubular transfer member 46 with its longitudinal axis X coincident with the longitudinal axis of the vial and stopper. It may be desirable, however, in certain applications to provide a nonconcentric arrangement and thus the present invention is not limited to the

concentric arrangement shown. The tubular transfer member 46 is accurately located and supported within the cap 50 by a radial rim 90 on the radial connector portion 58 as shown in Figure 2, which is received in a recess 92 in the cap. The cap further includes a V-shaped radially inwardly projecting rib 93, which is received in or snapped into a V-shaped groove 94 in the tubular transfer member as shown in Figure 2, providing accurate secure location of the tubular transfer member 46 in the cap 50.

The V-shaped interlock further permits preassembly of the tubular transfer member 46 and piercing member 48 in the cap 50 for bulk supply of the transferset and collar 52 to pharmaceutical companies, for example, for attachment to a vial, following filling of the vial with medicament, using the collar 52. In an alternative embodiment (shown in Figures 16 to 18 described below), the tubular transfer member is retained in the cap 350 for bulk supply by an interlocking rib and depression on opposed surfaces of the tubular transfer member and the cap, preferably spaced inwardly or proximately from the frangible connection. Further, in the embodiment described below, the piercing member is releasably retained in the tubular transfer member for bulk assembly and supply to the applicator responsible for filling the container or vial 22. Thus, as will be understood, various embodiments or means may be provided to retain the tubular transfer member 46 in the cap for bulk supply to pharmaceutical companies for later assembly on a vial within the purview of this invention. In the disclosed embodiment, the piercing member 48 includes a small ramped radial rib 73, spaced distally from the radial rib 75, which provides an interference fit with the internal surface 64 of the tubular transfer member 46 as best shown in Figures 5, 6, 9 and 10. This interference fit releasably retains the piercing member 48 in the tubular transfer member 46 upon assembly of the piercing member in the tubular transfer member. Thus, the components of the transferset 20 are retained as an assembly for bulk sale and use as described.

As set forth above, the collar 52 is most preferably formed of a malleable material such as aluminum to accommodate the thickness tolerances

of the stopper 34 and the rim portion 30 of the vial. The collar 52 includes a tubular portion 96 which surrounds the radial and longitudinal rim portions 78 and 88 of the cap 50, the planar radial rim portion 38 of the stopper and the rim portion 30 of the vial, a radially inwardly projecting portion 98 which overlies the radial rim portion 78 of the cap and a distal radial portion 100 which in the preferred embodiment is crimped into the reduced diameter neck 28 of the vial beneath the vial rim 30. In the disclosed embodiment, the collar 52 further includes a distal tubular portion 102 which surrounds the proximate end of the tubular portion 76 of the cap and the radial V-shaped external groove 82 as shown in Figure 2. This tubular portion 102 reduces the likelihood of accidental removal of the distal portion of the cap 50 and the distal end of the tubular portion 102 includes a rounded bead 104 which prevents the healthcare worker from engaging a sharp metal edge when removing the distal end of the cap during use. The distal removable portion of the cap is referred to hereinafter as the cover portion. Alternatively, the cover portion may be threaded onto the proximate end of the tubular portion 76 of the cap or connected by a "living hinge." However, the preferred embodiment of the cap 50 having a frangible connection 84 as shown in Figures 1 and 2 reduces the cost of the cap of the transferset and assures maintenance of the sterile conditions prior to use.

The method of assembling the transferset on a vial is best shown in Figures 9 and 10. The distal end 67 of the piercing member 48 is inserted into the proximate end of the tubular transfer member 46. As shown in Figure 10, the barrel portion 68 of the piercing member is first received in the larger internal diameter 66, wherein the radial rib 75 is generally equal to the diameter of the internal surface 66. The barrel portion 68 of the piercing member is then received in the smaller diameter surface 64 until the radial rib 75 engages the radial surface 65 between the internal surfaces 66 and 64 (Figure 10) as shown in Figure 1. The distal ends 62 of the tubular transfer member and 67 of the piercing member are then received in the open proximate end of the cap 50 and the tubular portion 76 of the cap 50 is then

received over the tubular portion 102 of the collar and the assembly is received over the radial planar rim portion 38 of the stopper 34 and the rim portion of the vial 22.

As noted above, the tubular transfer member 46 is accurately aligned within and supported by the cap 50. As shown in Figure 2, the radial rib 90 of the tubular transfer member is received within the radial groove 92 of the cap 50 and the V-shaped rib 93 on the cap snaps into the mating V-shaped groove 94 in the tubular transfer member. Further, the outer longitudinal rim 88 on the cap is received over the radial planar portion 38 of the stopper, such that the entire transferset assembly is accurately aligned on the stopper 34. Further, the piercing member 48 is accurately aligned and supported within the tubular transfer member 46, such that the relatively sharp piercing end 72 extends beyond the proximate end of the tubular transfer member 46 and the piercing member 48 is able to move toward the stopper, but is restrained from withdrawing from the stopper by the radial rib 75. As shown in Figures 9 and 10, the distal open end 100 of the tubular portion 96 is initially coincident with the tubular portion 76 as shown in phantom in Figure 1. Upon assembly, however, the end 100 is deformed or crimped into the neck portion 28 of the vial beneath the rim portion 30, permanently securing the transferset 20 on the vial 22. The radial rim portion 78 of the cap 50 is simultaneously compressed against the planar rim portion 38 of the resilient stopper as the distal end 100 of the collar 52 is crimped, such that the piercing end 72 of the piercing member 48 is pressed into the central portion 42 of the stopper, which causes the piercing end 72 to resiliently deform the unsupported central portion 42 of the stopper and, in the embodiment disclosed in Figures 1 to 4, the piercing end 72 may partially penetrate the central portion 42 of the stopper as shown in Figure 2. As will be understood, it may not be desirable in some applications for the piercing end 72 of the piercing member to partially penetrate the central portion 42 of the stopper when the transferset is assembled on the vial, particularly where the vial and transferset assembly of this invention is to be stored for an extended

period of time. In the alternative preferred embodiment of the transferset 320 shown in Figures 16 to 18, the piercing end 372 of the piercing member 348 is slightly rounded to avoid prepenetration of the stopper. Thus, the relative sharpness of the piercing end 72 and 372 of the piercing member 48 and 348 may be selected to either stretch or deform and prestress the central portion 42 of the planar rim portion 38 of the stopper 34 or deform and partially penetrate the central portion 42 of the stopper, as shown in Figures 1 to 4. Further, the sharpness of the pointed end 72 and 372 of the piercing member will depend upon the material used to form the piercing member 48 and the material may be selected to either partially pierce the stopper or simply deform and stretch the central portion 42 of the stopper.

The annular sealing lip 54 of the tubular transfer member 46 is also simultaneously driven into the central portion 42 of the stopper, stretching and prestressing the central portion 42 of the stopper as shown in Figure 2, and the sealing lips 86 of the cap 50 are driven into the resilient stopper providing an additional seal encircling the sealing lip 54. In the most preferred embodiment, the sharp piercing edge 56 of the sealing lip 54 of the tubular transfer member 46 slightly penetrates the central portion 42 of the stopper, providing an improved seal surrounding the communication between the interior 32 of the vial 24 and the tubular transfer member 46 when the piercing member 48 fully penetrates the stopper 34 as now described.

The transferset and vial assembly shown in Figure 1 is now ready for use. As set forth above, the transferset 20 may be assembled on the vial 22 and stopper 34 by the pharmaceutical company when the vial 22 is filled under sterile conditions. In a typical application, the vial is filled with a dry or powdered medicament which may be reconstituted into liquid form with an appropriate diluent or solvent solution prior to administration to a patient. In such applications, the diluent or solvent solution is first injected into the vial by a syringe, such as the conventional syringe 110 shown in Figures 4 to 6 and 9. A conventional syringe includes a tubular body portion 112, a tubular nozzle portion 114 which extends beyond the tubular body portion 112, a

plunger 116 having a head portion 118 having external seals 120, such as the O-ring seals shown in Figures 4 to 6. The plunger shaft 122 is generally cruciform in shape and may be integral with the head 118. The plunger 116 may be driven through or reciprocate through the interior 128 of the tubular body portion 112 to eject or withdraw liquid through the nozzle portion 114. A collar portion or tubular extension 129 of the tubular body portion 112 extends beyond the distal portion of the nozzle 114, the interior surface of which includes a female Luer lock or female threads which are normally used to connect a needle to the syringe. As shown in Figure 9, the shaft 122 of the plunger 116 generally includes a thumb or push button 132 and the body portion includes a radial, outwardly extending finger grip 134, such that the plunger head may be reciprocated through the tubular body portion 112 by gripping the radial finger grip 134 and the plunger head 118 is driven through the interior of the tubular body portion by engaging the push button 132 with the thumb. However, details of the design of various syringes are well known in the art and the transferset of this invention is not limited for use with any particular syringe design.

Prior to use of the vial and transferset of this invention by a healthcare worker, for example, the cover portion of the cap 50 must first be removed as shown in Figure 3. This is accomplished with the disclosed embodiment of the transferset 20 simply by twisting the distal end portion of the cap 50 as shown by arrow A in Figure 3. This twisting motion breaks the frangible connection 84 formed by the radial groove 82. The cover portion then comprises the distal portion of the tubular portion 76 and the closed distal end portion 80 as shown in Figure 3. The cover portion of the cap 50 is thus removed from the transferset 20 exposing the distal end 67 of the piercing member 48 and the tubular transfer member 46 as shown in Figure 3. As described above, the distal tubular portion 102 of the collar includes a rounded bead 104 which protects the fingers of the healthcare worker during removal of the cover portion of the cap 50 which will now be more fully understood from Figure 3.

The transferset 20 with the cover portion of the cap 50 removed is now ready for receipt of an IV set or a conventional syringe 110 as shown in Figure 4. First, the syringe 110 is coaxially aligned with the axis of the tubular transfer member 46. As shown, the diameter of the barrel portion 68 of the piercing member 48 is equal to or greater than the diameter of the nozzle portion 114 of the syringe, such that the nozzle portion 114 of the syringe will engage the distal end 67 of the piercing member 48.

The syringe 110 is then secured to the tubular transfer member 46 and the piercing portion 70 of the piercing member 48 is driven through the central portion 42 of the resilient stopper 34 as shown in Figures 5 and 6. As the tubular nozzle portion 114 of the syringe 110 is driven into the open distal end 64 of the tubular transfer member 46, the free end of the nozzle portion 114 is driven against the distal 67 of the piercing member 48, which drives the piercing end 72 through the central portion 42 of the stopper 34 as shown in Figure 5. The reduced diameter piercing portion 70 of the piercing member 48 is then driven through the central portion 42 of the stopper by threading the male thread of the Luer lock 60 at the distal end of the tubular transfer member 46 into the female thread 130 of the Luer lock on the extension or collar 129 of the syringe as shown in Figure 6. The threading of the syringe on the distal end of the tubular transfer member 46 drives the tubular nozzle portion 114 of the syringe 110 into the internal surface 64 of the tubular transfer member 46 and the free end of the tubular nozzle portion against the distal end 67 of the barrel portion 68 of the piercing member 48, which drives the piercing portion 70 of the piercing member through the central portion 42 of the stopper 34, establishing fluid communication through the external channel 74 and the interior 32 of the vial 22 as discussed more fully hereinbelow. As set forth above, the piercing of the center portion 42 of the stopper 34 by the piercing member 48 is facilitated by the circular sealing lip 54 on the proximate end of the tubular transfer member 46, which stretches and prestresses the unsupported central portion 42 of the stopper which overlies the tubular portion 36.

In a typical application of the transferset 20 of this invention, wherein the vial 22 contains a drug or medicament in dry or powdered form which is reconstituted by a diluent or solvent solution in the interior 128 of the syringe, the liquid diluent or solvent may now be transferred to the interior of the vial 22 simply by depressing the plunger 116 of the vial 110 as shown by arrow B in Figure 6. The liquid in the interior 128 of the syringe is thus ejected through the tubular nozzle portion 114 into the external channel 74 of the piercing member 48 into the tubular portion 34 of the stopper and thus into the interior 32 of the vial 22. As shown in Figure 8, which is a cross-section through the rim of the vial as shown in Figure 6, one configuration of the generally longitudinal channel 74 in the piercing member 48 is a V-shaped channel 74 which is relatively simple to manufacture. Further, the use of a V-shaped channel having an angle of about 15° to 60° does not materially weaken the piercing member and provides adequate communication between the interior 32 of the vial and the tubular transfer member 46 through the channel 74. A larger angle of about 45° to 60° may be preferred to limit manufacturing problems and avoid potential blockage of the groove. Further, the channel 74 may be of any convenient shape, including rectangular. As shown in Figure 8, the resilient elastomeric central rim portion 42 of the stopper will be deformed into and partially fill the channel 74 in the piercing member when the piercing portion 70 penetrates the stopper. The deformation and stretching of the central portion 42 of the stopper over the opening of the vial by the sealing lip 54 of the tubular transfer member however reduces the volume of elastomeric material which is deformed into the channel 74, thereby improving fluid communication through the external channel 74.

Generally, the liquid medicament is fully reconstituted by shaking the assembly as shown in Figure 7. The liquid medicament 136 may then be reaspirated into the same or a different syringe simply by withdrawing the plunger 116 into the tubular body portion 112 in the opposite direction from arrow B in Figure 6. It is important to note from Figure 7 that the liquid

medicament 136 is transferred from the vial 122 through the external channel 74, then from the external channel into the tubular transfer member 46 to the syringe (not shown). This should be contrasted with a needle having a small internal lumen or bore, wherein the liquid medicament below the piercing end (72 of the piercing member 48) cannot be reaspirated because the liquid must be transferred through the lumen of the needle. It should also be noted that the sharp end 56 of the annular or circular sealing lip 54 seals the communication between the tubular transfer member and the external channel 74 of the piercing member 48. This embodiment of the tubular transferset 20 of this invention and method of assembly thus provides several important advantages over the prior art as described above.

Figures 11 to 15 illustrate an alternative embodiment of the vial transferset and method of this invention, wherein the fluid pressure in the syringe is utilized to drive the piercing member through the central portion of the stopper rather than mechanical force as described above in regard to Figures 1 to 10. The components of the transferset 220 have been numbered in the same sequence as the transferset 20 shown in Figures 1 to 10, except that the components of the transferset 220 are numbered in the 200 series for ease of description and reference to Figures 1 to 10 described above. The vial 22, stopper 34 and syringe 110 may, however, be identical to the same components described above and are therefore numbered the same.

In the transferset 220 shown in Figures 11 to 15, the tubular transfer member 246 has an axial length which is greater than the axial length of the piercing member 248, such that the distal end 267 of the piercing member is recessed in the smaller diameter opening 264 of the tubular transfer member a distance equal to or greater than the length of the tubular nozzle 114 of the syringe 110. This can be accomplished either by reducing the axial length of the piercing member 248 or increasing the length of the tubular transfer member 246 as shown in Figures 11 to 15. Thus, in this embodiment, when the male Luer lock connection 260 on the tubular transfer member 246 is threaded into the female threads of the Luer lock of the tubular extension 129,

the tubular extension is received within the internal surface 264 of the tubular transfer member 246 without engaging the distal end 267 of the piercing member 248 as shown in Figure 11. This somewhat simplifies the connection of the syringe 110 to the tubular transfer member 246 compared to the embodiment of the transferset 20 shown in Figures 1 to 10 because the healthcare worker is not required to pierce the vial by urging the tubular nozzle portion 114 of the syringe against the distal end 267 of the piercing member although the embodiment of the transferset 20 is relatively easy to assemble.

The piercing end 272 of the piercing member 248 is then driven through the center portion 42 of the stopper 34 by moving the head 118 of the plunger 116 of syringe 110 toward the nozzle 114 of the syringe, which drives the liquid 140 in the tubular body portion 112 of the syringe against the radial rib 275 of the piercing member 248. As best shown in Figure 14, the radial rib 275 on the piercing member 248 of the transferset 220 shown in Figures 11 to 15 provides a fluid seal. That is, the radial sealing rim 275 extends into the external generally longitudinal channel 274 and the radial sealing rib 275 has an external diameter generally equal to or slightly greater than the internal diameter of the internal cylindrical surface 266 of the tubular transfer member 46. In this embodiment, the tubular transfer member includes a second enlarged bore 280 adjacent the proximate end having an internal diameter greater than the external diameter of the radial sealing rib 275. Thus, when the fluid pressure created by the plunger 118 of the syringe 110 drives the radial sealing rib 275 into the enlarged diameter portion 280, fluid is permitted to flow around the radial sealing rib 275 into the proximal portion of the channel 274 in the piercing member which has penetrated the central portion 42 of the stopper as shown in Figure 15.

The preferred alternative embodiment of the transferset 320 shown in Figures 16 to 18 operates and is assembled in the same manner as the embodiment of the transferset 20 shown in Figures 1 to 10. Further, the components of the transferset 320 are generally the same, including a tubular

transfer member 346, a piercing member 348, a generally cup-shaped cap 350 and a collar member 352. Thus, the components of the transferset 320 are numbered in the same sequence as the components of the transferset 20 shown in Figures 1 to 10 except that the components of the embodiment of the transferset 320 shown in Figures 16 to 18 are numbered in the 300 series. Where appropriate, the features of the components are also numbered in the same sequence for ease of reference to the above description and to avoid duplication of the description of this embodiment. Thus, for example, the tubular transfer member 346 includes an annular or circular sealing lip 354, a Luer lock connector 360 at its distal end, a first smaller internal diameter 364 and a larger proximate internal diameter 366 as described above. The following description of the components of the transferset 320 shown in Figures 16 to 18 will therefore be limited to the features which differ from the features of the transferset 20 shown in Figures 1 to 10.

First, as best shown in Figure 18, the tubular transfer member 346 includes an integral generally tubular connector portion 402, which in this embodiment, surrounds the proximate end of the tubular transfer member and is integrally joined to the remainder of the tubular transfer member at 404. The external surface of the connector portion 402 includes a radially projecting rounded rib 358 which is received in a groove 392 formed in the inner wall of the cap, providing a simplified snap-in interlock between the tubular transfer member 346 and the cap 350. The threaded Luer connector 360 on the tubular transfer member is also slightly modified; however, the Luer connector 360 is also conventional. The inner wall of the tubular portion 376 of the cap 350 also includes a plurality of sealing ribs 406 in this embodiment which engage the outer wall of the connector portion 402 of the tubular transfer member 346 which seal the connection between the cap and the tubular transfer member and prevent contamination of the transferset.

The piercing member 348 has also been modified in this embodiment. First, as best shown in Figure 17, the piercing end 372 of the piercing member 348 is slightly rounded to prevent premature penetration of the planar

rim portion 38 of the stopper 34 shown, for example, in Figure 1. That is, the slightly rounded piercing end 372 will deform and stretch the planar rim portion 38 of the stopper, but will not partially penetrate the rim portion as shown in Figure 1. The piercing end 372, however, is "relatively sharp" and will pierce the planar rim portion of the elastomeric stopper 34 when the piercing member 348 is driven into the stopper as described above. Further, the external channel 374 in the piercing member 348 terminates short of the piercing end as shown in Figure 17, such that the channel 374 includes a rounded end wall 408 spaced slightly from the proximate end of the relatively sharp piercing end 372. Terminating the external channel 374 a few millimeters (e.g. 7 mm) short of the piercing end 372 strengthens the piercing end 372 for penetration of the planar rim portion 38 of the stopper. In this embodiment, the piercing member 348 is releasably retained in the tubular transfer member by an interlocking rib and groove as best shown in Figures 16 and 17. In the disclosed embodiment, the piercing member includes an arcuate groove 410 adjacent the radial rib 375 and the internal surface 364 of the tubular transfer member 346 includes an interlocking arcuate rib 412 as shown in Figure 16 which releasably retains the piercing member 348 in the tubular transfer member 346. In the disclosed embodiment of the piercing member 348, the barrel portion includes two spaced flats 414 which receive the mold ejector pins (not shown) which make it easier to remove the piercing member from the mold, but the flats do not form a functional part of the invention.

Thus, as described above, the transferset 320 shown in Figures 16 may be preassembled in bulk with the collar for distribution to pharmaceutical companies, for example, for attachment to a vial under sterile conditions. The barrel portion 368 of the tubular transfer member further includes spaced flats which receive ejector pins in a mold to simplify release of the piercing member 348 from the mold, but are not functional in the transferset assembly 320. Finally, in this embodiment, the distal end 367 of the piercing member 348 is rounded which also simplifies molding of the piercing member 348.

The components of the transferset 328 are assembled and secured to a vial 22 as described above. Upon assembly of the transferset 320 as shown in Figure 16, the end 300 of the tubular portion 396 is crimped into the reduced diameter neck portion 28 of the vial as described above. The assembly of the transferset 320 on the vial drive the sealing lips 354 and 386 of the tubular transfer member into the planar radial rim portion 38 of the stopper, sealing the assembly. The cover portion of the cap 350 is then removed by twisting the distal end, breaking the frangible connection 384 as described. The transferset may then be utilized to transfer fluid to or from the vial by connecting a syringe 110 or IV set (not shown) to the Luer lock connector 360 as described above. As set forth above, the operation of the transferset 320 in transferring fluid to or from a vial is the same as described above in regard to Figures 1 to 10.

As will be understood by those skilled in the art, various modifications may be made to the vial transferset and method of this invention within the purview of the appended claims. For example, the tubular transfer member 46, 246 and 346 may be polygonal, in which case, the barrel portion 68, 268 and 368 of the piercing member 48, 248 and 348 may be similarly polygonal and the tubular portion 76, 276 and 376 of the cap may either by cylindrical or polygonal. Further, the collar 52, 252 and 352 may be formed of any suitable malleable material or may also be formed of a suitable plastic although in the disclosed embodiment the collar may be formed of aluminum. The piercing member and tubular transfer member may be formed of various materials including, for example, a medical grade polycarbonate having the appropriate strength and suitable for sterilization. The cap 50, 250 and 350 may also be formed of a medical grade polycarbonate. Further, as set forth above, the external generally longitudinal channel 74, 274 and 374 in the piercing member 48, 248 and 348 respectively, may be of various configuration including, for example, a spiral or a discontinuous longitudinal groove. Having described the vial transferset and method of this invention, it is now claimed as set forth below.

CLAIMS

1. A fluid transfer assembly for establishing fluid communication between a syringe or the like and a sealed vial, said vial having an open end, a rim surrounding said open end, a reduced diameter neck portion adjacent said rim and a pierceable stopper received in and sealing said vial open end, said stopper having a rim portion received over said vial rim, said transfer assembly comprising:

a tubular transfer member having an open proximate end sealingly supported on said stopper rim portion in alignment with said vial open end and an open distal end adapted to receive a syringe tip in sealed communication;

a piercing member received within said tubular transfer member reciprocally supported by an internal surface of said transfer member, said piercing member having a piercing end opposite said stopper rim portion adapted to pierce said stopper and an opposed distal end;

a cap having a proximate radial rim portion adjacent an open end, a tubular portion surrounding said tubular transfer member and a closed distal end enclosing said open distal end of said transfer member and said distal end of said piercing member; and

a collar having a radial portion received over said cap radial rim portion, a tubular portion surrounding said cap radial rim portion and said vial rim and a distal radial portion received in said vial neck portion of said vial beneath said vial rim permanently securing said transfer assembly to said vial.

2. The fluid transfer assembly defined in Claim 1, wherein said piercing member includes an external generally longitudinal channel providing communication between said vial open end and said tubular transfer member when said piercing member pierces said stopper.

3. The fluid transfer assembly defined in Claim 1, wherein said piercing member piercing end extends beyond said tubular transfer member and said piercing member is releasably restrained in said tubular transfer member with said sharp piercing end partially penetrating said stopper.

4. The fluid transfer assembly defined in Claim 1, wherein said tubular portion of said cap includes a radial groove weakening the wall of said tubular portion for removal of said closed distal end from said fluid transfer assembly prior to use.

5. The fluid transfer assembly defined in Claim 1, wherein said open distal end of said transfer member includes an external Luer connector for receiving an Luer connector of said syringe.

6. The fluid transfer assembly defined in Claim 1, wherein said radial rim portion of said tubular transfer member includes a projecting circular sealing lip surrounding said tubular portion of said transfer member which engages said stopper rim portion, deforming and stretching said stopper rim portion over said vial open end, sealing the communication between said vial open end and said tubular transfer member when said piercing member pierces said stopper.

7. The fluid transfer assembly defined in Claim 6, wherein said circular lip of said transfer member extends generally perpendicular to said radial rim portion of said transfer member and includes a pointed edge which bites into said rim portion of said stopper.

8. The fluid transfer assembly defined in Claim 6, wherein said radial rim portion of said cap includes a circular sealing lip surrounding said tubular portion of said cap which engages said stopper rim portion in sealed

relation providing a seal to maintain the sterility of said fluid transfer assembly when assembled on said vial.

9. The fluid transfer assembly defined in Claim 1, wherein said tubular portion of said cap includes a radial groove weakening the wall of said tubular portion for removal of said closed distal end of said cap and said collar radial portion includes a tubular portion overlying said groove in said cap.

10. The fluid transfer assembly defined in Claim 1, wherein said piercing member distal end is cylindrical having an external diameter generally equal to an internal surface of said tubular transfer member adjacent said distal end of said transfer member supporting said piercing member generally perpendicular to said rim portion of said stopper.

11. The fluid transfer assembly defined in Claim 10, wherein said piercing member includes a radial lip received in an enlarged counter bore in said tubular transfer member which releasably retains said piercing member in said tubular transfer member with said sharp piercing end partially penetrating said stopper prior to use.

12. The fluid transfer assembly defined in Claim 1, wherein said tubular transfer member proximate end includes a radial flange which interlocks with said cap.

13. The fluid transfer assembly defined in Claim 1, wherein said collar is formed of a relatively thin malleable metal and said tubular portion is crimped into said vial neck beneath said vial rim permanently securing said transfer assembly to said vial.

14. A fluid transfer assembly for establishing fluid communication between a syringe and a sealed vial, said vial having an open end, a rim surrounding said open end, a reduced diameter neck adjacent said rim, and a pierceable stopper received in and sealing said vial open end, said stopper having a rim portion received over said vial rim, said transfer assembly comprising:

a generally tubular transfer member having an open proximate end sealingly supported on said stopper rim in generally coaxial alignment with said vial open end and an open distal end adapted to receive a syringe in sealed communication;

a piercing member received within said tubular transfer member reciprocally supported by an internal surface of said transfer member, said piercing member having a relatively sharp piercing end deforming said stopper radial rim portion and an external channel providing communication between said vial and said tubular transfer member when said piercing member penetrates said stopper;

a cup-shaped cap having a tubular portion surrounding said transfer member and a removable cover portion enclosing said open distal end of said transfer member and said distal end of said piercing member; and

a collar having a radial portion received over said cap radial rim portion, a tubular portion surrounding said cap radial rim portion and said vial rim and a distal radial portion received in said vial neck portion beneath said vial rim permanently securing said transfer assembly to said vial.

15. The fluid transfer assembly defined in Claim 14, wherein said collar is formed of a relatively thin malleable material and said distal radial portion of said collar is crimped in said vial neck of said vial beneath said vial rim permanently securing said transfer assembly to said vial.

16. The fluid transfer assembly defined in Claim 14, wherein said tubular portion of said cap includes a radial groove weakening the wall of said tubular portion for removal of said cover portion prior to use.

17. The fluid transfer assembly defined in Claim 14, wherein said open distal end of said tubular transfer member includes an external Luer connector for receipt of a Luer connector of said syringe.

18. The fluid transfer assembly defined in Claim 14, wherein said radial rim portion of said tubular transfer member includes a projecting circular sealing lip surrounding said tubular portion of said transfer member which engages said stopper rim portion, said projecting lip portion stretching said rim portion of said stopper over said vial open end sealing the communication between said vial open end and said tubular transfer member when said piercing member pierces said stopper and reducing deformation of stopper material into said piercing member external channel, thereby improving fluid communication through said channel.

19. The fluid transfer assembly defined in Claim 18, wherein said circular sealing lip of said transfer member includes a pointed edge which bites into said rim portion of said stopper, whereby said tubular fluid transfer member is sealingly supported on said stopper rim portion.

20. The fluid transfer assembly defined in Claim 18, wherein said radial rim portion of said cap includes a circular sealing lip which surrounds said tubular portion of said cap, said sealing lip of said cap engaging said stopper rim portion in sealed retention providing a seal for maintaining sterility of the interior of said fluid transfer assembly.

21. A method of transferring fluid medicament between a conventional sealed vial and a second container, said vial having an open end,

a rim surrounding said open end, a reduced diameter neck adjacent said rim and a pierceable stopper received in and sealing said vial open end, said stopper having a rim portion received over said vial rim, said second container including a tubular connector portion, said method comprising:

mounting a fluid transfer assembly on said vial, said transfer assembly including a tubular transfer member having an open proximate end adapted to be sealingly supported on said stopper rim of said vial in alignment with said vial open end and an open distal end having a connector adapted to be connected to said connector portion of said second container, a piercing member received in said tubular transfer member reciprocally supported by an internal surface of said tubular transfer member, said piercing member having a generally short piercing end and an external channel, and a tubular collar, said method including mounting said fluid transfer assembly on said vial by securing said collar on said neck portion of said vial beneath said rim with said tubular transfer member sealingly engaging said stopper rim portion and said piercing member coaxially aligned with said vial open end and said piercing end adjacent said stopper;

attaching said connector portion of said second container to said connector on said tubular transfer member, driving said piercing member generally sharp piercing end through said stopper rim portion, said external channel in said piercing member establishing fluid communication between said vial and said second container through said tubular transfer member, thereby permitting transfer of fluid from said second container to said vial or from said vial to said second container.

22. The method of transferring fluid medicament between a conventional sealed vial and a second container as defined in Claim 21, wherein said fluid transfer assembly includes a cup-shaped cap having a radial rim portion adjacent an open end, said method including mounting said cap with said rim portion opposite said stopper radial rim portion, a tubular portion surrounding said transfer member and a cover portion enclosing said

open distal end of said transfer member and said distal end of said piercing member, said cover portion attached to said tubular portion by a frangible connector, said method including mounting said fluid transfer assembly on said vial under sterile conditions with said cup-shaped cap enclosing said transfer assembly maintaining said tubular transfer member and said piercing member under sterile conditions until use, then removing said cover portion by breaking said frangible connector, then attaching said syringe to said tubular transfer member.

23. The method of transferring fluid medicament between a conventional sealed vial and a second container as defined in Claim 21, wherein said collar is formed of a relatively thin malleable metal having a tubular portion and a radial portion, said method including telescopically receiving said collar over the components of said fluid transfer assembly and said vial rim with said radial portion overlying said components of said transfer assembly and said tubular portion receiving said vial rim, then crimping a free end of said tubular portion beneath said vial rim extending into said vial neck permanently securing said transfer assembly on said vial.

24. The method of transferring fluid medicament between a conventional sealed vial and a second member as defined in Claim 23, wherein said tubular transfer member includes a generally circular sealing lip surrounding said tubular portion of said transfer member which is generally aligned with said tubular portion, said method including compressing said sealing lip against said rim portion of said stopper as said collar is crimped on said vial, stretching said rim portion of said stopper before piercing of said stopper by said piercing member.

25. The method of transferring fluid medicament between a conventional sealed vial and a second member as defined in Claim 24, wherein said circular sealing lip of said tubular transfer member has a pointed

edge, wherein said method includes pressing said sealing lip against said rim portion of said stopper, such that said sealing lip pointed edge bites into said stopper rim portion providing an improved seal of the communication between said vial open end and said tubular transfer member when said piercing member pierces said stopper.

26. The method of transferring fluid medicament between a conventional sealed vial and a second container as defined in Claim 24, wherein said piercing member is releasably retained in said tubular transfer member with said piercing end extending beyond said tubular transfer member, said method including compressing said sealing lip of said tubular transfer member and said piercing end of said piercing member against said rim portion of said stopper as said collar is crimped on said vial, said piercing end of said piercing member resiliently deforming said rim portion of said stopper.

27. The method of transferring fluid medicament between a conventional sealed vial and a second container as defined in Claim 21, wherein said connector on said tubular transfer member and said connector portion of said second container are mating threaded connectors and said connector portion of said second container extends beyond a body portion of said second container, said method including threading said threaded connector portion of said second container on said threaded connector of said tubular transfer member thereby driving said nozzle portion of said syringe against said distal end of said piercing member and said sharp end of said piercing member through said stopper rim portion, thereby establishing said fluid communication between said second container and said vial.

28. The method of transferring fluid medicament between a conventional sealed vial and a second container as defined in Claim 21, wherein said second container is a syringe having a tubular body portion

initially filled with fluid, a plunger retracted within said syringe tubular body portion, and a reduced diameter tubular nozzle portion extending beyond said tubular body portion, said piercing member including a radial sealing portion engaging an interior surface of said tubular transfer member, said method including attaching said syringe on said connector on said tubular transfer member thereby establishing fluid communication between said nozzle portion of said syringe and said distal end of said tubular transfer member, then driving said plunger of said syringe toward said nozzle portion, driving fluid against said radial sealing portion of said piercing member and driving said piercing end of said piercing member through said stopper, thereby establishing said communication between said syringe and said vial.

29. The method of transferring fluid medicament between a conventional sealed vial and a second container as defined in Claim 21, wherein said fluid transfer assembly includes a cup-shaped cap, said cap including a tubular portion having an internal diameter greater than said tubular transfer member, and an open proximate end, a radial rim portion adjacent said open end and a closed distal end, said tubular transfer member including a circular sealing lip surrounding said tubular portion of said tubular transfer member, said method including assembling said fluid transfer assembly by inserting said piercing member in said tubular transfer member with said piercing end adjacent said proximate end of said tubular transfer member, receiving said cap over said tubular transfer member with said closed distal end enclosing said distal ends of said tubular transfer member and said piercing member, then assembling said tubular transfer member, piercing member and cap on said rim portion of said stopper with said tubular transfer member and said piercing member in generally coaxial alignment with said open end of said vial, generally perpendicular to said stopper rim portion, then securing said assembly on said vial with said collar and simultaneously compressing said proximate end of said tubular transfer member against said stopper, compressing said circular sealing lip against said stopper rim portion,

stretching said lip portion over said vial open end and sealing communication between said piercing member external channel and said tubular transfer member when said piercing member pierces said stopper.

30. The method of transferring fluid medicament between a conventional sealed vial and a second container as defined in Claim 29, wherein said piercing member is assembled in said tubular transfer member with said piercing end extending beyond said tubular transfer member proximate end, said method then including compressing said tubular transfer member on said stopper rim portion with said piercing end of said piercing member deforming said stopper.

31. The method of transferring fluid medicament between a conventional sealed vial and a second container said radial rim portion of said cap includes a circular sealing lip surrounding said tubular portion of said cap adjacent to said tubular portion, said method including pressing said circular sealing lip of said cap against said rim portion of said stopper, providing a seal surrounding said piercing member.

32. A method of assembling a fluid transfer assembly on a conventional vial for transferring fluid between said vial and a second container, said vial having an open end, a rim surrounding said open end, a reduced diameter neck adjacent said rim, and a resilient pierceable stopper received in and sealing said vial open end, said stopper having a rim portion received over said vial rim, said method comprising:

inserting an elongated piercing member having a piercing end and an opposed distal end into a tubular fluid transfer member having an internal surface supporting said piercing member for telescopic movement in said tubular fluid transfer member, said tubular fluid transfer member including an open proximate end adjacent said piercing end of said piercing member having a projecting sealing lip and an open distal end;

inserting said tubular fluid transfer member into a cup-shaped cap, said cup-shaped cap including an open proximate end which receives said tubular fluid transfer member and said piercing member, a radial rim portion adjacent said open proximate end and a closed distal end adjacent said distal ends of said tubular fluid transfer member and said piercing member; and

securing said fluid transfer assembly on said vial rim with a collar by locating said cap, tubular fluid transfer member and piercing member on said rim portion of said stopper with said tubular fluid transfer member and piercing member generally coaxially aligned with said vial opening, said collar having a radially inwardly projecting portion overlying said rim portion of said cap, a tubular portion surrounding said radial portion of said cap and said vial rim and a radial portion received in said vial neck beneath said rim and simultaneously compressing said sealing lip of said tubular fluid transfer member against said rim portion of said stopper, stretching said stopper rim portion over said vial opening and sealing communication between said tubular fluid transfer member and said vial opening when said piercing end of said piercing member pierces said stopper.

33. The method of assembling a fluid transfer assembly on a conventional vial as defined in Claim 32, wherein said method includes assembling said piercing member in said tubular fluid transfer member such that said piercing end extends beyond said proximate end of said tubular fluid transfer member and said piercing member restrained from moving further into said tubular fluid transfer member, said method further including compressing said piercing end of said piercing member into said rim portion of said stopper, deforming said stopper as said sealing lip of said tubular fluid transfer member is compressed into said stopper rim portion.

34. The method of assembling a fluid transfer assembly on a conventional vial as defined in Claim 32, wherein said radial rim portion of said cap includes a projecting sealing lip surrounding said tubular portion of

said cap and said method including compressing said sealing lip of said cap against said rim portion of said stopper as said sealing lip of said tubular fluid transfer member is compressed into said rim portion of said stopper, providing a seal maintaining the sterility of said fluid transfer assembly.

35. The method of assembling a fluid transfer assembly on a conventional vial as defined in Claim 32, wherein said method further includes transferring fluid from said vial to a conventional syringe or vice versa, wherein said distal end of said tubular fluid transfer member includes a threaded connector, said method including removing said closed distal end of said cap, threading the threaded connector of a conventional syringe to said threaded connector of said tubular fluid transfer member and transferring fluid by moving the plunger of the syringe.

36. The method of assembling a fluid transfer assembly on a conventional vial as defined in Claim 35, wherein said syringe includes a tubular portion, a plunger having a head reciprocally mounted in sealed relation within said tubular portion and a reduced diameter nozzle portion extending beyond said tubular portion in fluid communication with said tubular portion, said distal end of said tubular fluid transfer member having a threaded connection and said syringe having a mating threaded connection, said method including threading said syringe threaded connector on said threaded connector of said tubular fluid transfer member, thereby driving said nozzle portion of said syringe against said distal end of said piercing member and said piercing end of said piercing member through said stopper rim portion, thereby establishing fluid communication between said vial and said syringe through said tubular transfer member and permitting transfer of fluid from said syringe to said vial or from said vial to said syringe by movement of said plunger in said tubular portion of said syringe.

37. The method of assembling a fluid transfer assembly on a conventional vial as defined in Claim 32, wherein said second container is a syringe which includes a tubular portion, a plunger having a head reciprocally mounted in sealed relation within said tubular portion and a reduced diameter nozzle portion opposite said plunger head in communication with said tubular portion, wherein said syringe is initially filled with fluid and said plunger is retracted within said syringe tubular portion and said piercing member distal end is generally closed, said method including attaching said syringe connector to said connector on said tubular fluid transfer member, establishing communication between said nozzle portion of said syringe and said distal end of said tubular fluid transfer member, then driving said plunger of said syringe toward said nozzle portion, driving fluid against a radial sealing portion of said piercing member and driving said piercing end of said piercing member through said stopper and thereby establishing fluid communication between said syringe and said vial.

38. A method of securing a fluid transfer assembly on a conventional vial and stopper assembly, said vial having an open end, a radial rim portion surrounding said open end and a reduced diameter neck portion adjacent said open end, said stopper formed of an elastomeric material and including a tubular portion received in said vial open end and an integral generally planar rim portion overlying said vial rim portion, said method comprising:

assembling said fluid transfer assembly on said stopper generally planar rim portion, said fluid transfer assembly including a generally flat annular surface overlying said planar rim portion of said stopper having a circular sealing lip projecting from generally flat annular surface;

securing said fluid transfer assembly on said vial stopper assembly with a collar formed of a malleable metal, said collar including a tubular portion having an inside diameter slightly greater than an outside diameter of said vial rim portion and an integral radially inwardly projecting annular portion, said

method including disposing said collar tubular portion over said fluid transfer assembly and said vial rim portion with said collar radially inwardly projecting annular portion receiving said generally flat annular surface of said fluid transfer assembly, compressing said circular sealing lip projecting from said flat annular surface into said stopper generally planar rim portion and crimping a distal end of said collar tubular portion into said vial neck beneath said vial rim.

39. The method of securing a fluid transfer assembly on a conventional vial and stopper assembly as defined in Claim 38, wherein said circular sealing lip includes a sharp edge having a diameter greater than an inside diameter of said vial open end, such that said circular sealing lip overlies a portion of said stopper generally planar rim portion which overlies said vial radial rim portion, said method including compressing said sharp edge of said circular sealing lip into said stopper generally planar rim portion while said distal end of said collar is crimped into said vial neck portion, causing said sharp edge of said sealing lip to penetrate said stopper generally planar rim portion sealing the communication between said vial open end and said fluid transfer assembly.

40. The method of securing a fluid transfer assembly on a conventional vial and stopper assembly as defined in Claim 38, wherein said circular sealing lip has a diameter less than an inside diameter of said vial open end and said stopper tubular portion, such that said circular sealing lip overlies an unsupported central portion of said stopper generally planar rim portion, said method including compressing said circular sealing lip into said stopper generally planar rim portion as said distal end of said collar tubular portion is crimped into said vial neck portion, said circular sealing lip stretching and prestressing said central portion of said stopper planar rim portion.

41. The method of securing a fluid transfer assembly on a conventional vial and stopper assembly as defined in Claim 40, wherein said fluid transfer assembly includes a piercing member having a piercing end supported in said fluid transfer assembly generally perpendicular to said stopper planar rim portion and said piercing end of said piercing member extending beyond said generally flat annular surface, said method including compressing said piercing end of said piercing member into said stopper generally planar rim portion to partially, but not totally penetrate said generally planar rim portion of said stopper as said collar tubular portion is crimped into said vial neck portion.

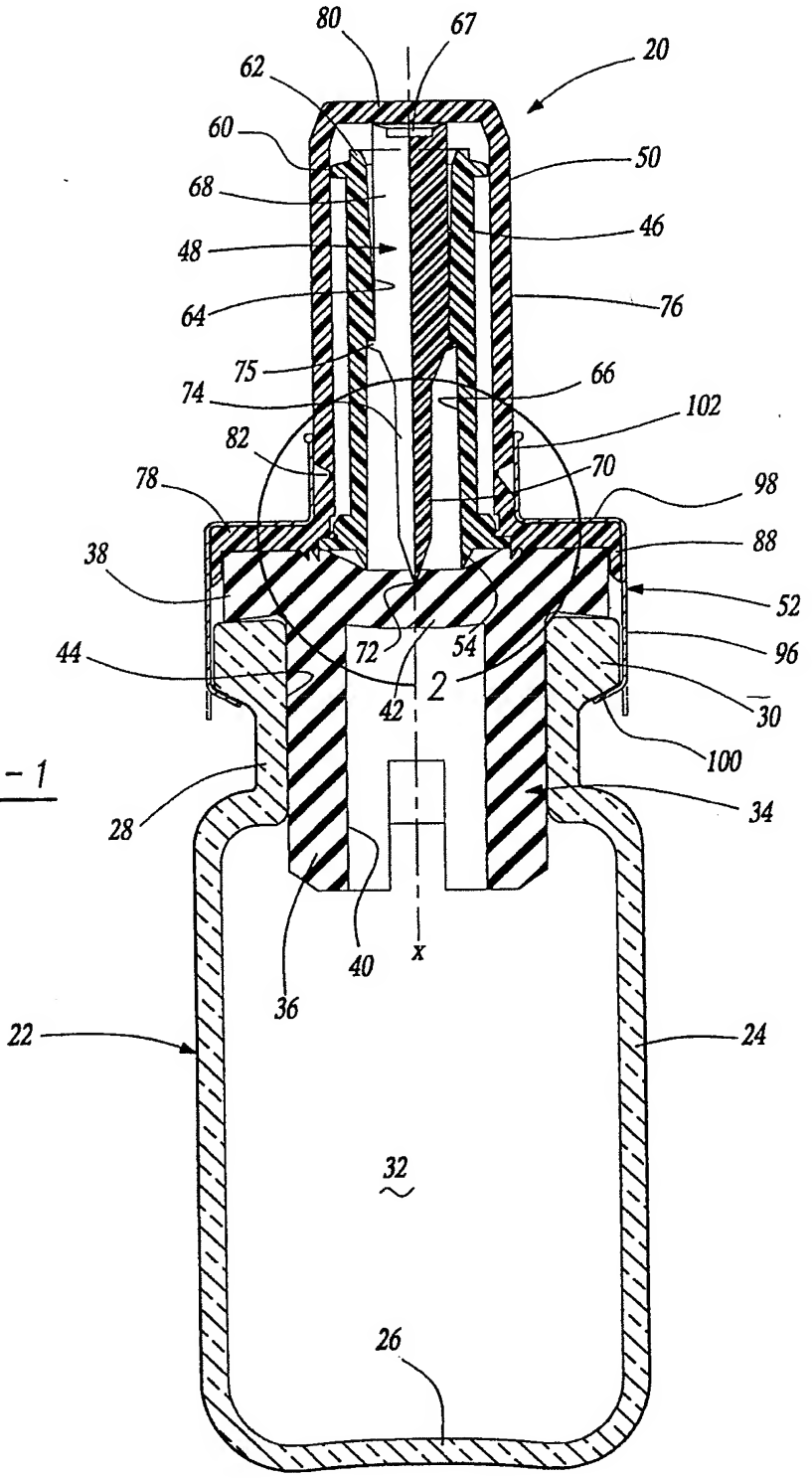
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Fig - 1

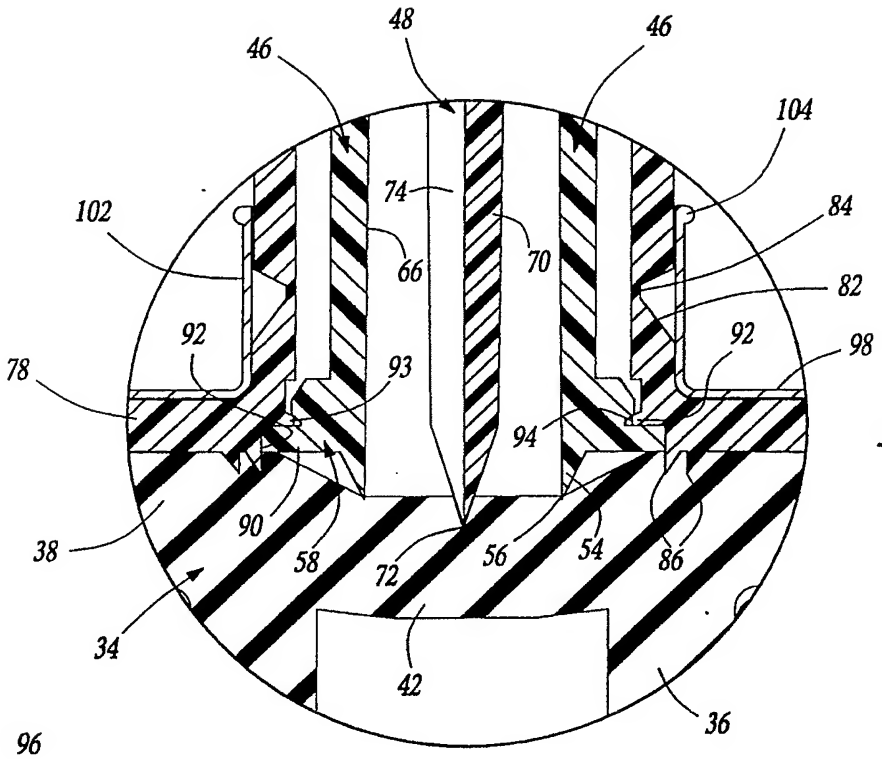
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Fig-2

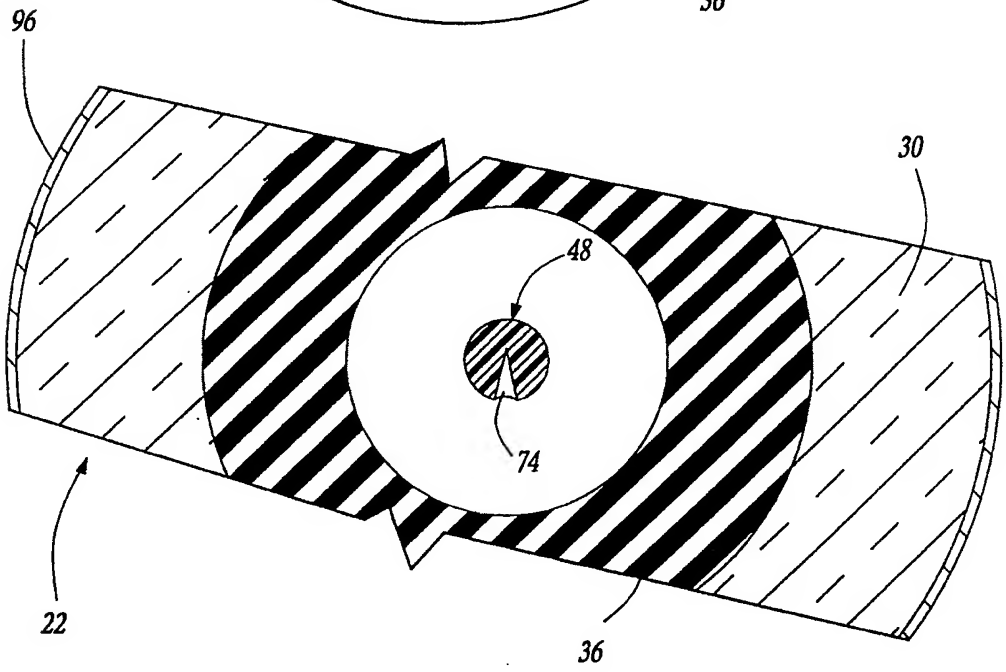
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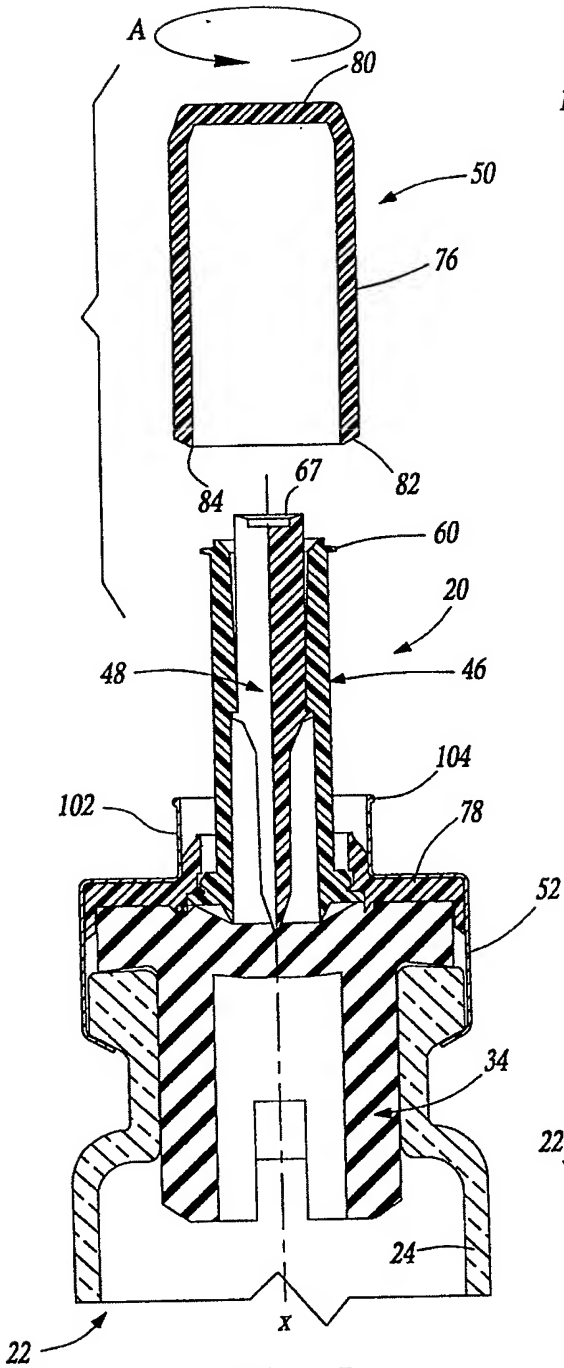
Fig-8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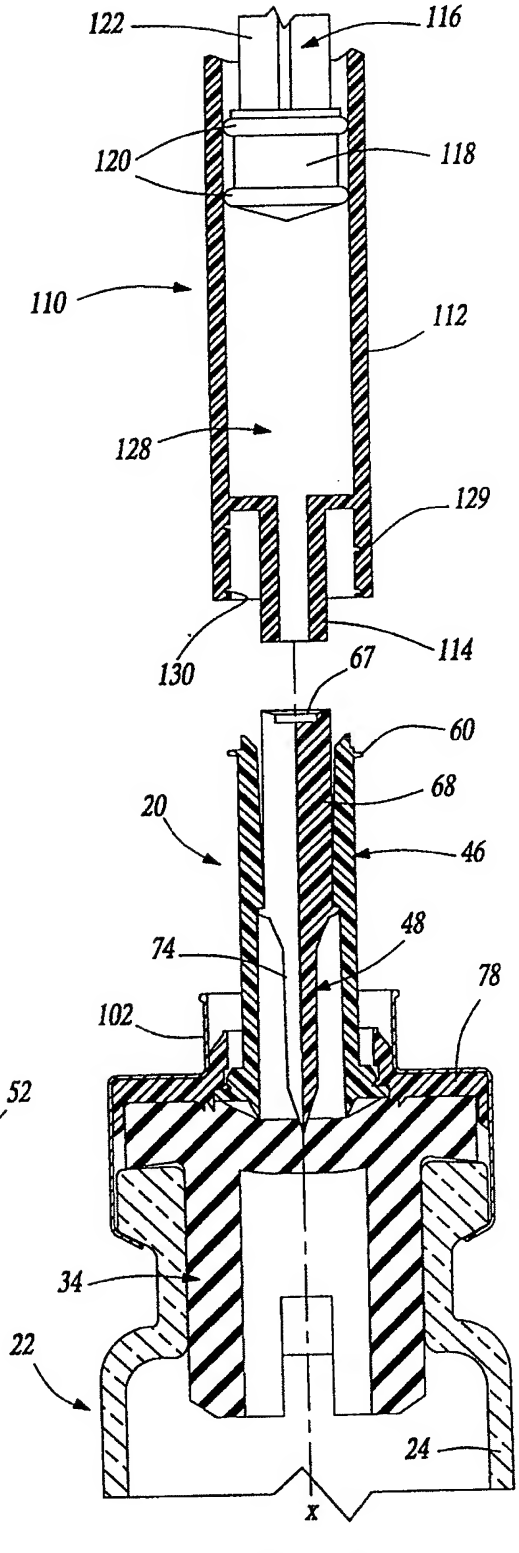
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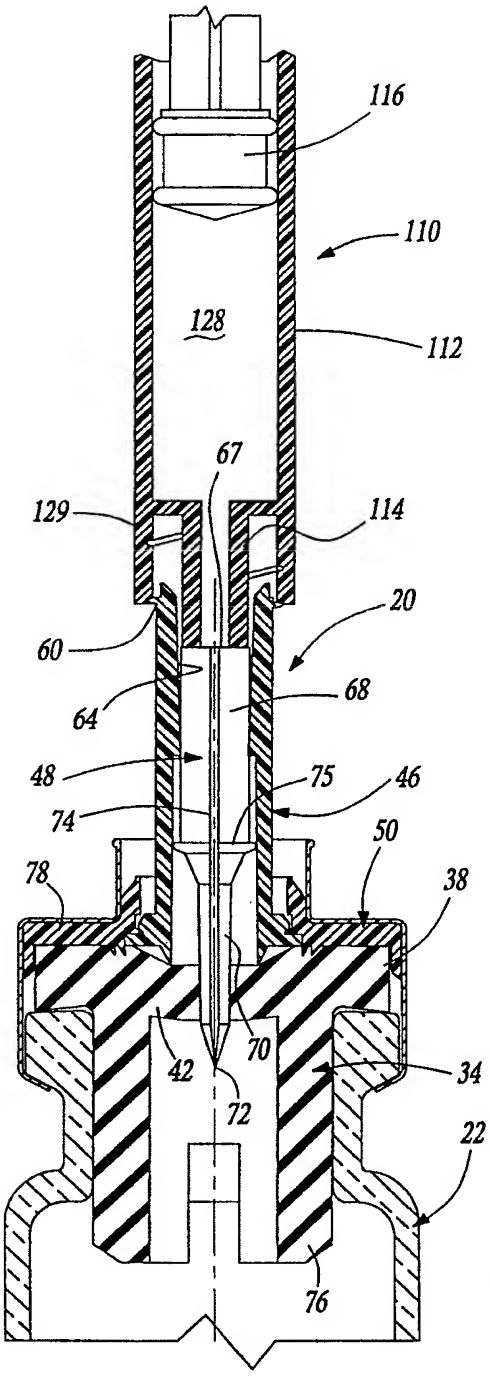
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Fig-5

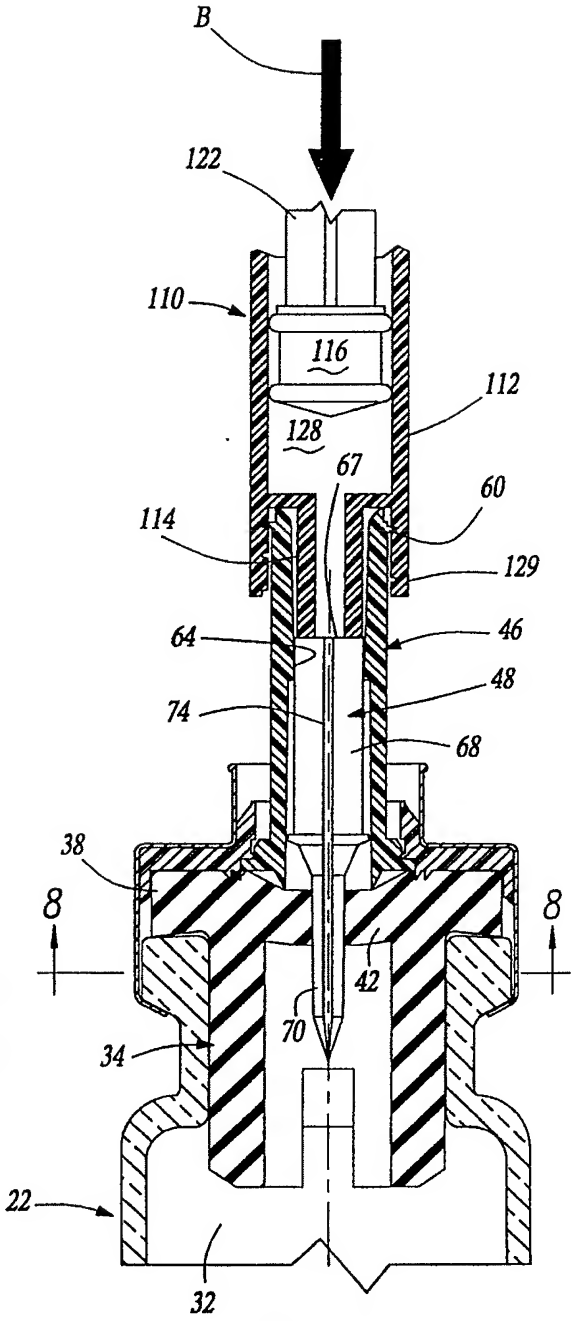
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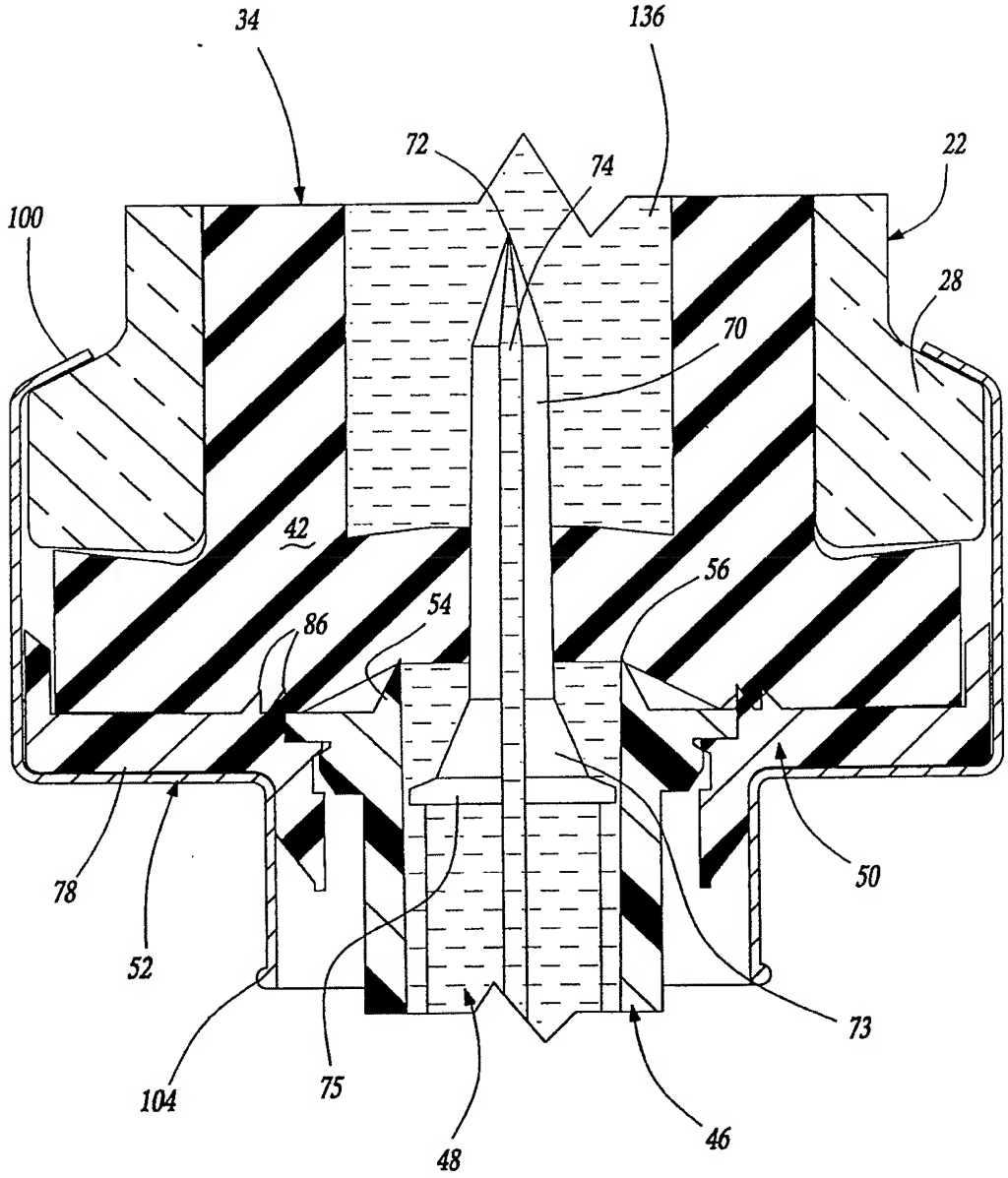
Fig-6



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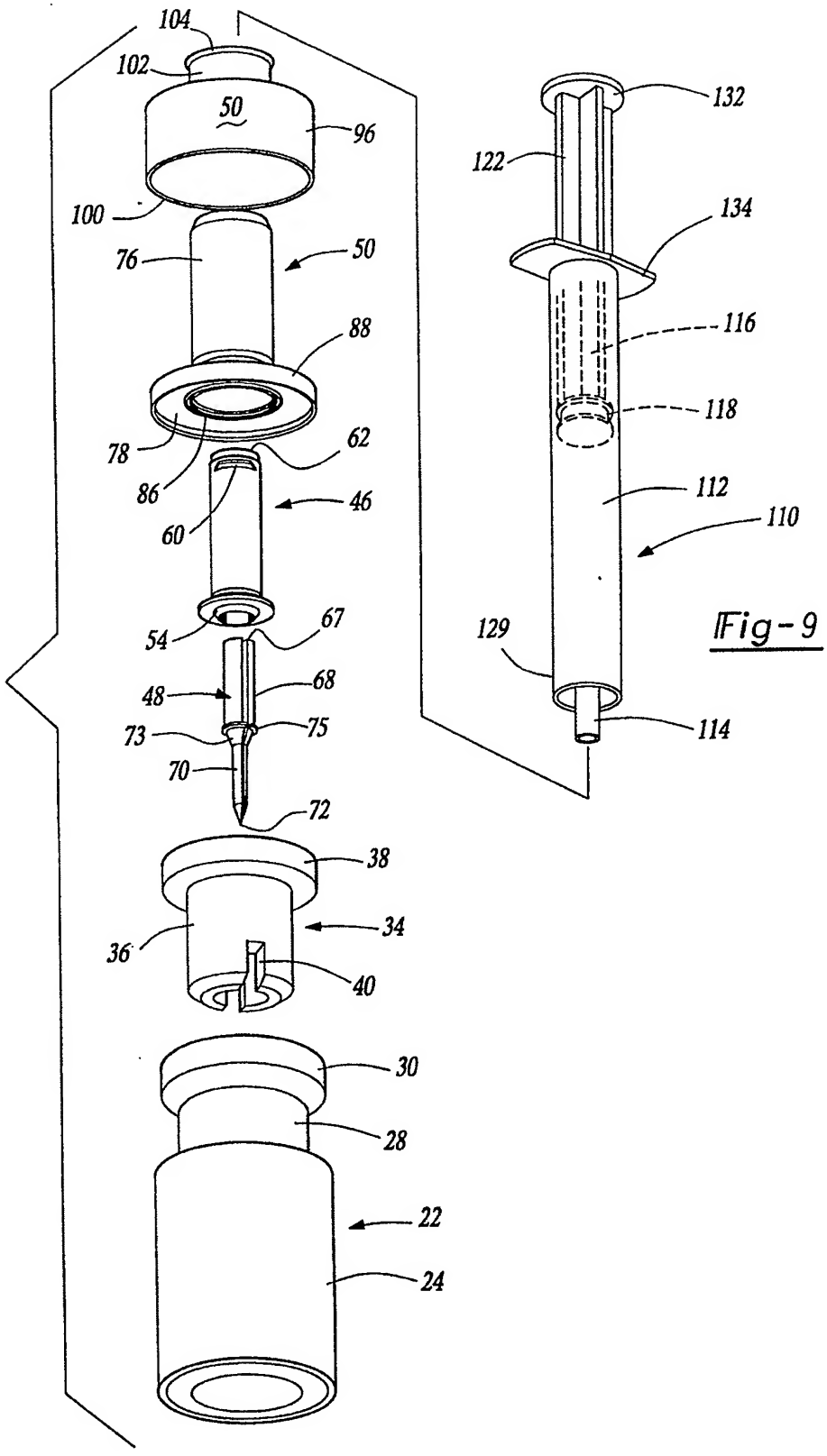
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Fig-9

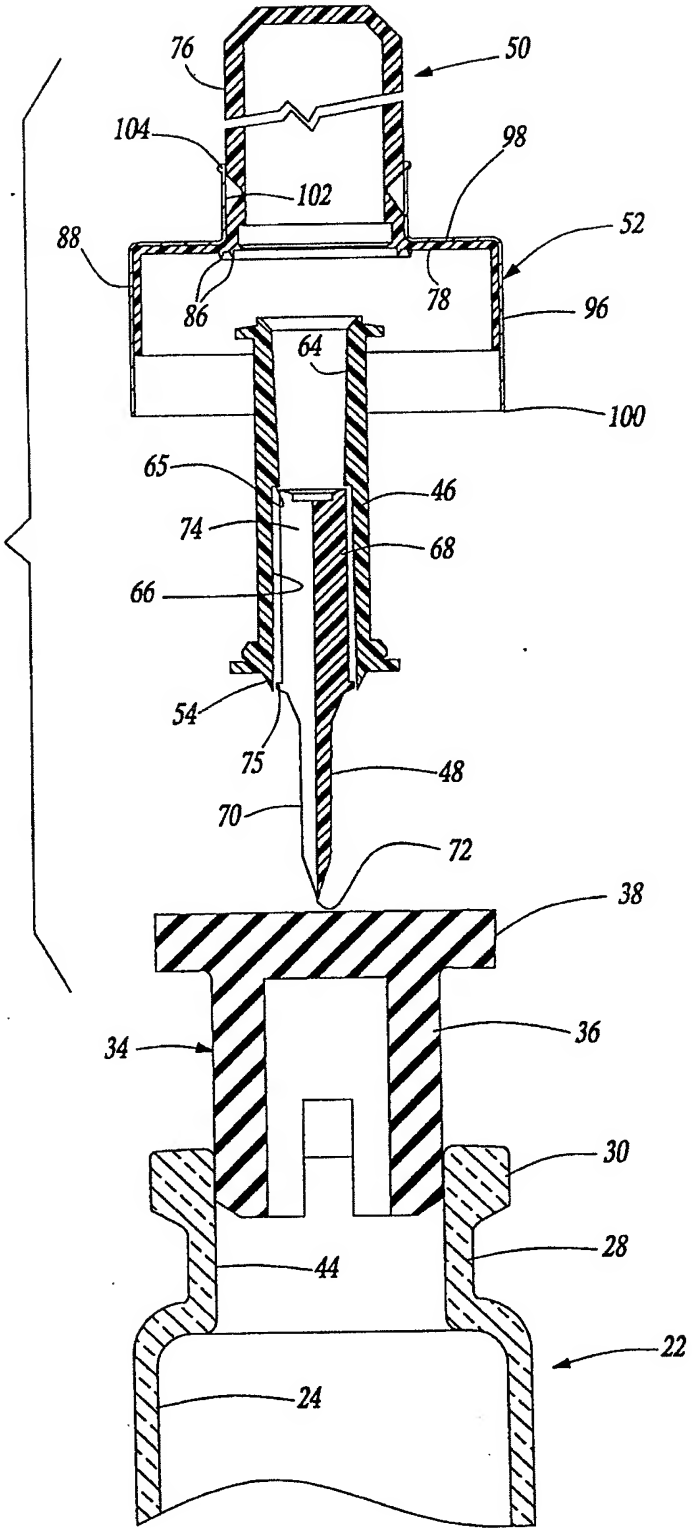
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Fig-10

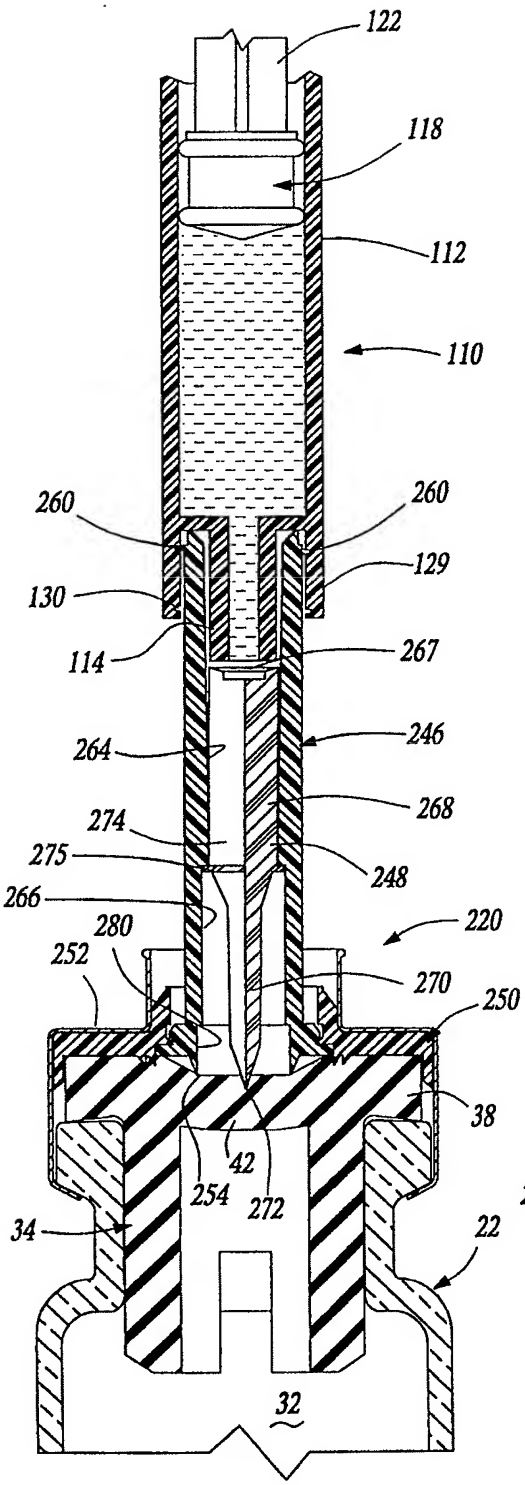
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Fig-11

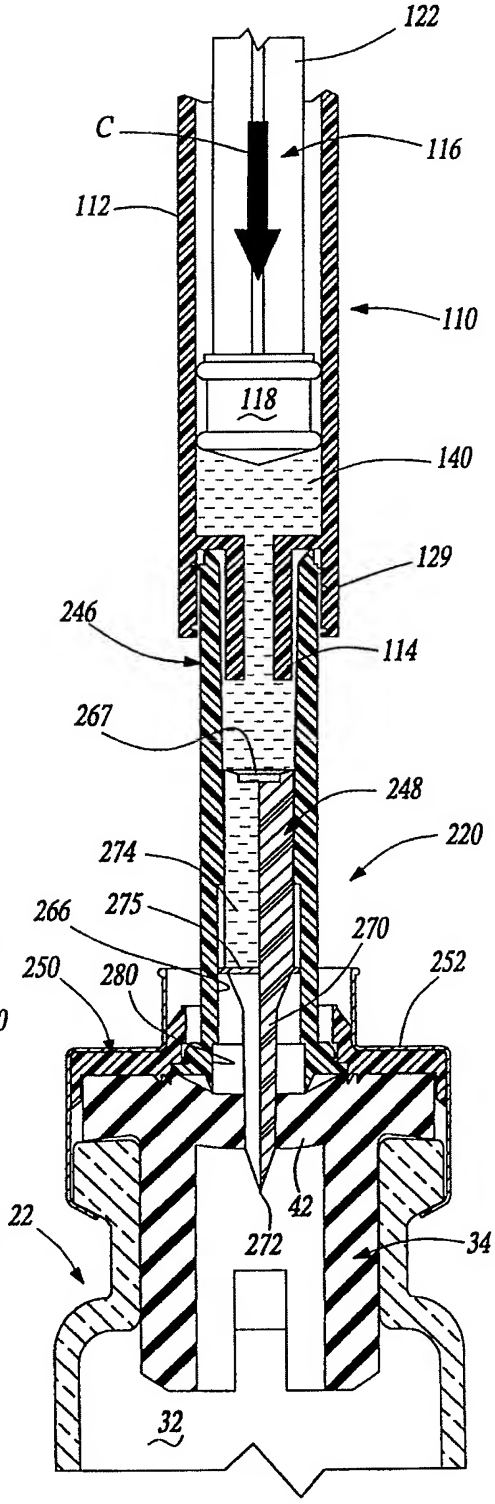
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Fig-12

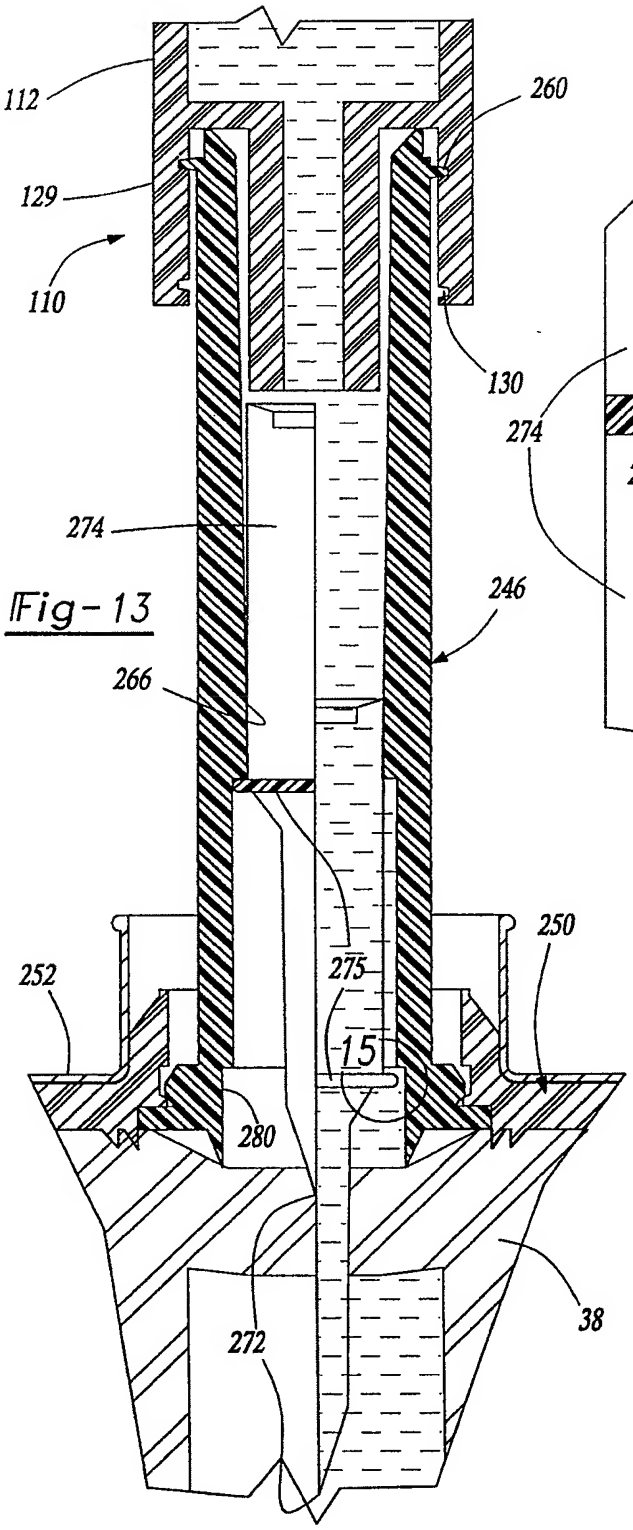

Fig-13

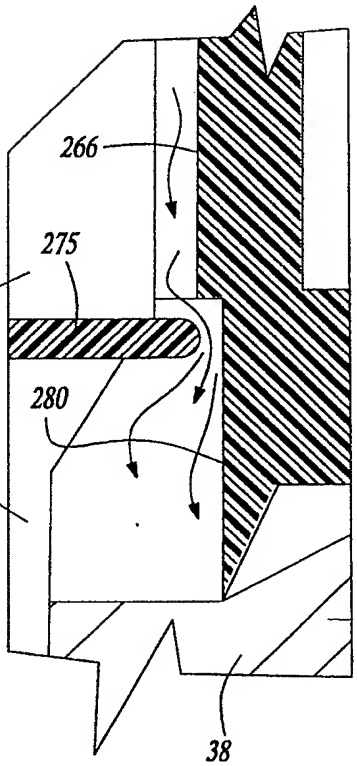

Fig-15

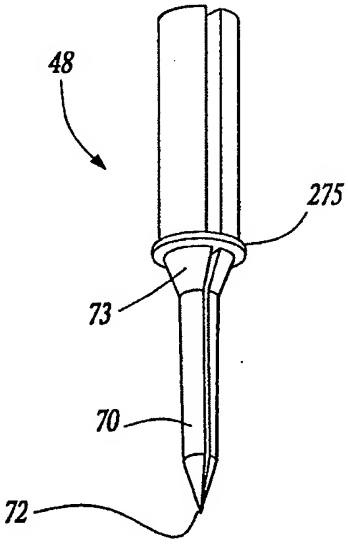

Fig-14

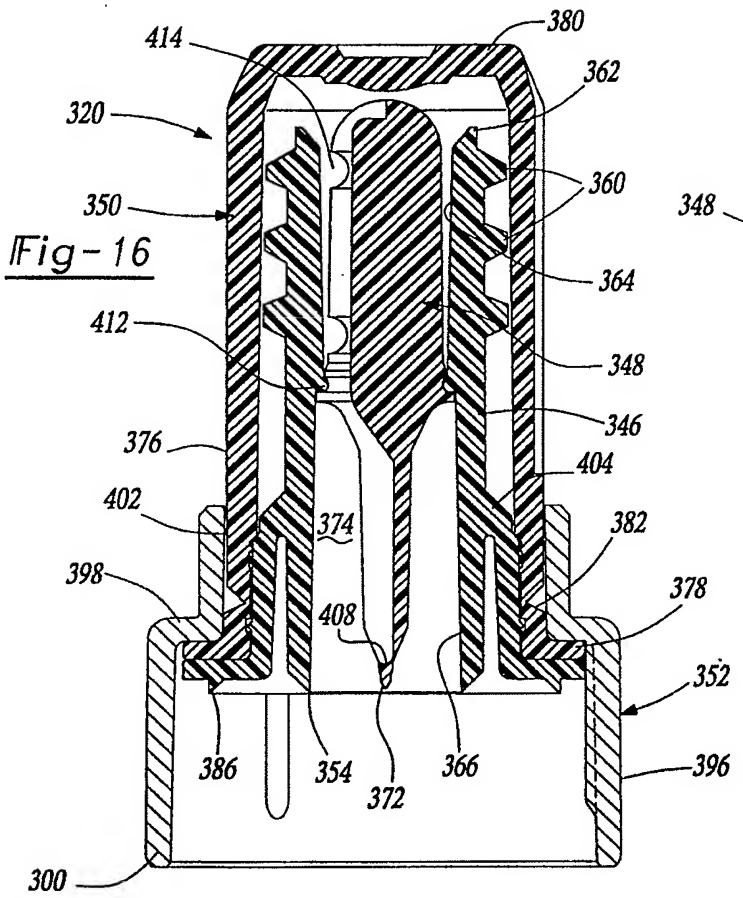

Fig-16

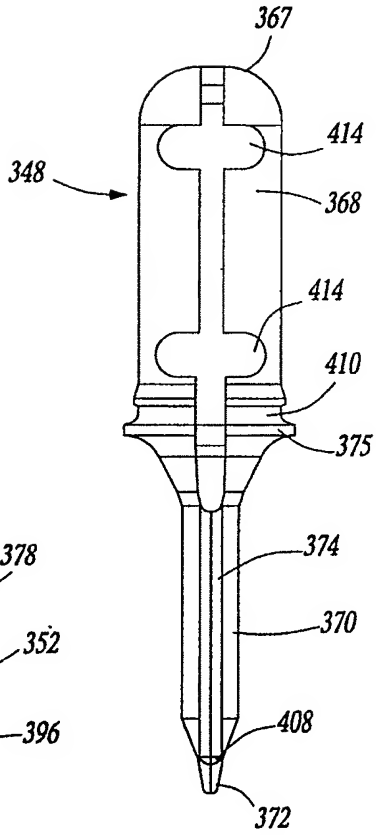

Fig-17

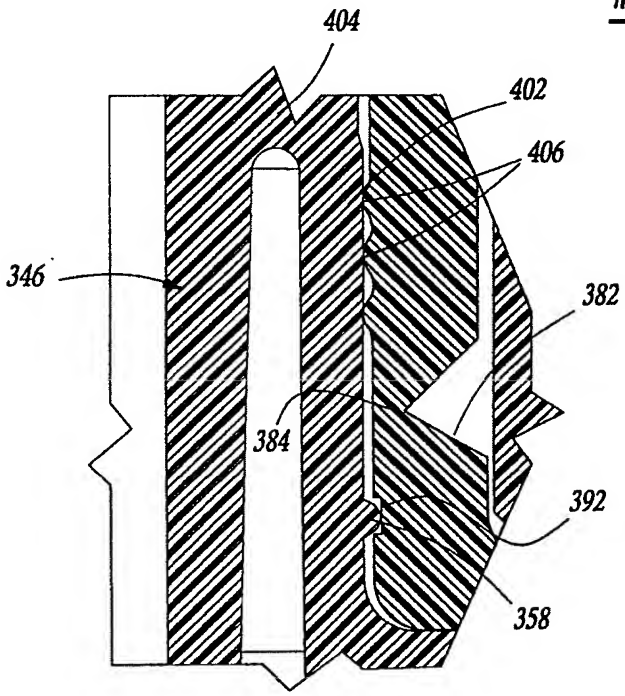

Fig-18

INTERNATIONAL SEARCH REPORT

Internal Application No
PCT/US 99/04077

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61J1/20

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61J

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,P	FR 2 753 624 A (BIODOME) 27 March 1998 see the whole document ---	1,4,14, 16,21, 27-29, 31,32,38
X,P	WO 98 37854 A (ABBOTT LAB) 3 September 1998 see page 8, line 15 - page 19, line 29; figures 1-14 ---	1,14,21, 31,32,38
X,P	WO 98 32411 A (SMITHKLINE BEECHAM BIOLOG ;THILLY JACQUES (BE)) 30 July 1998 see page 12, line 9 - page 17, line 10; figures --- -/--	1,14,21, 31,32,38

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
4 June 1999	11/06/1999

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Baert, F

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INTERNATIONAL SEARCH REPORT

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	US 3 977 555 A (LARSON ROGER R) 31 August 1976 see column 2, line 60 - column 5, line 23; figures 2,6,7	1,14,21, 31,32,38
A	US 5 358 501 A (MEYER GABRIEL) 25 October 1994 cited in the application see abstract; figures	1
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INTERNATIONAL SEARCH REPORT

Information on patent family members

Internat. Application No
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